EXHIBIT A

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

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IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	:	MDL NO. 2875
	:	HON. ROBERT B. KUGLER
THIS DOCUMENT APPLIES TO ALL CASES	:	

- CONFIDENTIAL INFORMATION -
SUBJECT TO PROTECTIVE ORDER

- - -

September 23, 2021

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Videotaped remote deposition of JANICE K. BRITT, Ph.D., taken pursuant to notice, was held via Zoom Videoconference, beginning at 9:11 a.m., EST, on the above date, before Michelle L. Gray, a Registered Professional Reporter, Certified Shorthand Reporter, Certified Realtime Reporter, and Notary Public.

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E X H I B I T S

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E X H I B I T S (Cont'd.)

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E X H I B I T S (Cont'd.)

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DEPOSITION SUPPORT INDEX

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Direction to Witness Not to Answer

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None.

Request for Production of Documents

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Stipulations

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None.

Questions Marked

PAGE LINE

None.

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THE VIDEOGRAPHER: We are now on the record. My name is Judy Diaz, I'm a legal videographer for Golkow Litigation Services.

Today's date is September 23rd, 2021, and the time is 9:11 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation MDL, for the United States District Court, District of New Jersey.

The deponent is Dr. Janice K. Britt, Ph.D.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely.

All counsel will be noted on the stenographic record.

The court reporter is Michelle Gray and will now swear in the witness.

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... JANICE K. BRITT, Ph.D., having been first duly sworn, was examined and testified as follows:

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EXAMINATION

- - -

BY MR. SLATER:

Q. Good morning, Dr. Britt.

A. Good morning.

Q. I'm going to take your deposition now. You understand that, right?

A. Yes, I do.

Q. Do you understand that you're now under oath and you must tell the truth every time you're asked a question?

A. I do.

Q. Please provide truthful answers and complete answers as well,

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okay?
A. Can you repeat the question?
Q. Sure. We'll expect also not only truthful answers, but complete answers, okay?
A. Correct, yes, yes.
Q. If I ask you a question that you don't understand for any reason or don't feel like you can answer it in a truthful and complete way, just tell me.
A. Okay.
Q. I have a habit -- I can mispronounce scientific terminology. I may ask a question in a way that you don't hear what I say, whatever the reason may be.
You can just tell me what -- that you couldn't hear, or what doesn't make sense or what you want me to clarify, and we'll work it out. And then I'll try to arrive at a question that makes sense to you so that you could answer truthfully. Okay?
A. Okay.

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Q. During the course of the deposition, there may be objections. That happens. I'm sure you've seen it. That's just lawyers preserving their rights to the future as to whether questions were asked the right way.
There's never going to be, for example, a suggestion of how to answer a question through an objection. That would be completely inappropriate.
I want you to just understand, if an objection is made, let the lawyer talk. Let the lawyers speak if they have to discuss it. And then I would assume you'll be directed to answer unless it's something that is, you know -- falls within a privilege or something. But I just don't want you to be thrown off by objections, because it's going to happen. It's inevitable, okay?
A. Okay. I understand.
MR. SLATER: Chris, let's put up as Exhibit 1, the deposition notice, please.

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(Document Marked for identification as Exhibit Britt-1.)
BY MR. SLATER:
Q. Doctor, Exhibit 1 on the screen is the deposition notice for this deposition. Have you seen that document?
A. I'm going to pull it up on my screen, because I -- it's far away here.
Q. Sure. And if you have a hard copy there, you're welcome to look at any hard copies of any documents we use on the screen. In fact, if you tell me you have the actual document, like I'm hoping you have your report there -- I'm assuming you do -- you can just use the document. We don't have to put it on the screen. Okay?
A. Okay. I also --
Q. Let me ask you a question. When you say you're putting it on your screen, that's not the screen of the laptop that's recording the -- that's

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doing the Zoom. You're looking at a different laptop?
MR. GALLAGHER: Just refresh.
THE WITNESS: Can you repeat the question? I'm having a hard time understanding.
BY MR. SLATER:
Q. You're looking at your own laptop? Is that my understanding? Is that correct?
A. That is correct.
Q. Okay. Why can't you look at this on the screen?
A. It is too far away. I cannot see it. I'm about 25 feet away.
MR. GALLAGHER: So she's got the Golkow exhibit platform, and so that way she has the full document.
MR. SLATER: That's fine.
BY MR. SLATER:
Q. Obviously, Dr. Britt, I wouldn't have to tell you this, nobody

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can be communicating with you by the -- electronically. You know that right, right?
A. Yes. Of course.
Q. Okay.
A. Yeah, it came up. Okay. It pulled up.
Q. Have you seen this -- I'll start over. On Exhibit -- rephrase.
Exhibit 1 is the notice to take videotaped oral deposition. Have you seen this document?
A. Yes.
Q. Did you read it?
A. Yes.
MR. SLATER: Let's go now to Exhibit 2, defendants' responses and objections to the notice of deposition.
(Document Marked for identification as Exhibit Britt-2.)
BY MR. SLATER:
Q. Have you seen this document?

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A. Okay. It's open.
Q. Have you seen this document prior to now?
A. No, I do not believe I've seen this document.
Q. Do you have any information as to how the lawyers who hired you responded to the deposition notice in this document, or is this the first time you're getting any information on that?
A. I sent them information that -- in response to the notice. And if I was missing a document, they'd let me know. If it didn't match up with my report. So I'm assuming that's what this is based on. I haven't reviewed this document. Do you want me to review?
Q. Yeah, let me ask you a question. Why is it that you can't use Zoom on your laptop and then just look at the documents as we put them up and then take a look at the documents if you want to go into the Golkow document repository? Why can't you do that?

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Every other witness has seemed to be able to do that.
MR. GALLAGHER: I don't understand the issue. I mean, she's looking at the Golkow -- exhibits on the Golkow --
THE WITNESS: Can you read that on the screen?
MR. REEFER: Yeah -- no, I cannot read it.
MR. SLATER: Well, you'd read it if it was on the laptop in front of you, Dr. Britt.
THE WITNESS: No, I can see it in front of me on the laptop. But I cannot see it on the screen. It's too far away.
And it's zoomed -- it's zoomed in the screen.
MR. SLATER: All right. Well, we're going to continue like this for the time being. But we may have to have a conversation.
BY MR. SLATER:

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Q. I understand you can't see it on the screen across the room. But if you're doing it as I'm doing it, where my laptop is what I'm using Zoom on, and the document is on the laptop right in front of you, you can see it perfectly fine, because the laptop is two feet from your eyes. That's my point. And I'm not sure why you're not doing that.
MR. GALLAGHER: Adam, the witness can look at the full exhibit. And every witness has had access to all the exhibits through the Golkow link on their platform.
I mean, she you can flip through the whole document. There's nothing wrong with what she's doing.
MR. SLATER: Well, we'll take it up.
MR. GALLAGHER: It's much better.
MR. SLATER: Okay.

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BY MR. SLATER:
Q. Dr. Britt, your answer is that you have not seen these responses that were served on us, right?
A. Can you repeat the question?
Q. You have not seen this document before? You haven't seen the responses that were provided to us in response to our deposition notice before right now; is that correct?
A. Correct. I have not seen the document that is on the screen right now.
Q. Let's go to Page 2, Request Number 1. "Copies of all invoices for work performed in connection with any consultation or expert work performed for or on behalf of any defendant or their counsel with regard to any issues in this MDL, included but not limited to for the review of documents, review in consultation with regard to plaintiff experts, preparation of Dr. Britt's report and preparation for deposition or

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trial."
Did you provide all your invoices to counsel?
A. I believe counsel had the invoices themselves. I provided them to them when they were billed, and so they had those invoices.
Q. Did you look at the invoices that were provided to us to make sure they were complete?
A. No, I did not.
Q. We'll come back to the invoice in a little while.
Have you ever performed any consulting or other work for any of the defendants in this litigation other than in this litigation?
A. No, I've not consulted or performed any work for any of the other -- for any of the defendants in this litigation that I'm aware of besides this case.
Q. Have you ever -- so the answer to my question is no? Is the

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answer no?
A. Yes, the answer is no.
Q. Have you ever worked with any of the law firms that are defending the defendants in this litigation to your knowledge, for example, Duane Morris, Greenberg Traurig, any of the law firms you're aware of that are defending the manufacturers here?
Have you ever worked with them other than in this case?
A. I believe I worked with Duane Morris before.
Q. What was that in connection with?
A. I don't remember what it would have been in regards to.
Q. Was it litigation?
A. It was either litigation or consulting.
Q. When did that happen?
A. I do not recall the dates. I would have to look into them.
Q. Was it after 2000?

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A. I do not recall.
Q. Was it after 1980?
A. Well, yes, it would have to be after 1980.
Q. So sometime in the last 41 years, but you can't be more specific than that?
A. It would probably be in the last 15 years.
Q. Do you recall what lawyer at Duane Morris or lawyers you worked with?
A. I do not.
Q. Do you keep records of who you do work for? I assume your companies keep records of who you've billed in the past and worked with.
A. My company?
Q. Yes. Your company.
A. Yes, I assume -- yes, I have billing records.
Q. So if you wanted to figure out when you did work with Duane Morris in the past, you could figure that out, right?

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A. Yes, I could potentially do that, yes.
Q. But your testimony under oath is you have no recollection of when or with regard to what you may have ever worked with Duane Morris?
A. Yes.
MR. GALLAGHER: Objection to form of the question. Objection to form.
BY MR. SLATER:
Q. Is that right?
A. Yes. Yes, that is correct.
Q. Did you prepare for this deposition?
A. Yes.
Q. Did you meet with lawyers from Duane Morris as part of your preparation?
A. Yes.
Q. Did you meet with lawyers from any other law firm as part of your preparation?
A. Yes.

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Q. Who?
A. Jason from -- I'm not sure of his law firm.
Q. Do you know his last name?
A. I do not know his last name.
Q. Tell me every lawyer that you've met with in connection with this litigation that you've ever spoken with or met with?
A. In person or in Zoom calls, I assume?
Q. Both. In any way. Either Zoom, telephone, or in person?
MR. GALLAGHER: Objection to form.
You can answer.
THE WITNESS: Patrick, Rick Ball. They're both with Duane Morris. And then Jason who I mentioned earlier. I am not sure of his firm. Alan, who's also with Duane Morris. Zoe, who also works with Jason.
I've spoken with Lauren and

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Coleen at Duane Morris. I've spoken with or corresponded with lawyers from Teva and Hetero, Aurobindo, e-mail or over the phone.
BY MR. SLATER:
Q. Do you know who those lawyers are?
A. Can you repeat your question?
Q. Yeah. Who were the lawyers? I'm asking you for names.
A. I do not recall their names.
Q. Have you been retained by any of the lawyers or any of the manufacturers for any other matters or any other subjects since the time that you were first contacted in this case?
MR. GALLAGHER: Objection to form.
You can answer that yes or no. But I would caution you if there's something that's confidential --

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MR. SLATER: It's a yes or no question. It's not privileged.
MR. GALLAGHER: That's what I said. She can answer it yes or no.
THE WITNESS: Can you repeat the question?
BY MR. SLATER:
Q. Sure. From the time that you were first contacted about the valsartan contamination litigation, have you been retained by any of the lawyers or manufacturers connected with this case with regard to any other matter?
A. No.
Q. Have they discussed any potential other matters with you?
A. No.
Q. Are you hoping to get more business from these lawyers and these manufacturers in the future?
MR. GALLAGHER: Objection to form.
THE WITNESS: No.

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BY MR. SLATER:
Q. You don't want to get more business from these other lawyers? Rephrase.
You don't want to get business in the future from the lawyers of the manufacturers on the defense side in the future?
MR. GALLAGHER: Objection to form.
THE WITNESS: No, that's not a concern of mine.
BY MR. SLATER:
Q. Let's go through the rest of the deposition notice. Let's go to Number 2 on Page 3. Copies of any notes, i.e., written or electronic reflecting consulting or litigation work that has not been documented in invoices.
First of all, do any such notes exist?
A. Which number are we on?
Q. Number 2.
A. On page? Which page?

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Q. I'm sorry, Doctor. Are you having trouble following along with me? I said Page 3, second request.
A. You're breaking up. So I'm having trouble hearing every fourth word or so.
MR. SLATER: Is it that bad for everybody? Because if it is, I'm going to go on to -- I'm going to go on to my hot spot on my phone.
MR. GALLAGHER: It has been breaking up just a bit.
BY MR. SLATER:
Q. Well, I'm getting notes from people that they seem to be able to hear me, Doctor. So if there's an issue, do you need to get closer to the microphone perhaps?
A. That's fine. Maybe if you can turn your volume up a little bit, or you can turn your volume up.
Q. Request Number 2 on Page 3. We're going to go in order. Request

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Number 2, do you have any such notes?
MR. GALLAGHER: Objection to form.
THE WITNESS: I have the report, and I have the documents that were supposed to be sent out. I don't have any notes.
BY MR. SLATER:
Q. Did you take any notes in the course of your work in this matter?
A. No.
Q. Did you put Post-It notes or highlight or mark up any of the documents that you were provided?
MR. GALLAGHER: Objection to form.
THE WITNESS: I may have my highlighted some of the papers that I reviewed.
BY MR. SLATER:
Q. Do you have those papers with you that have highlighting on them?
A. No. I just have the papers that I submitted.

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Q. Well, where are your -- the original documents that you actually highlighted? Where are they located?
A. On our computers -- my files are located in a file at our company.
Q. So you're saying you electronically highlighted the documents, not physically?
A. Yeah. It's electronically highlighted.
MR. SLATER: Counsel, we're going to request that any documents that Dr. Britt has that --
BY MR. SLATER:
Q. Well, let me ask this question. I'll ask this of Dr. Britt.
Dr. Britt, do you know if the highlighted versions of the documents that you were provided, meaning those that you highlighted yourself electronically, were provided to us when your reliance materials were provided?
A. No. They were just my

copies of the report -- of the articles.
MR. SLATER: So I'm going to ask, if possible, frankly this morning, as soon as possible, if any documents Dr. Britt highlighted or marked in any way, can be immediately transferred to our team so we can look at them and potentially use them in this deposition.
Is that something that can be accomplished?
MR. GALLAGHER: We'll take your request under advisement. We can deal with that at a break.
BY MR. SLATER:
Q. Did you put notes of any nature on those documents that you were reviewing as part of your work in this case, meaning either you typed something in or you put some sort of a note electronically on the document? Did you do that in addition to highlighting any of the documents?

A. No. I had just highlighted maybe words, a couple words on a document.
Q. You said that you only highlighted a couple of words in one document?
A. I would highlight, if there was something that was -- like an odds ratio or a conclusion or, you know, something that I wanted to recall of an article. I would have highlighted the entire article.
Q. Let's go to Request 3. Copies of any notes or other documentation, including PowerPoints, from any presentations, seminars, or classes given by Dr. Britt with regard to the risks and benefits of any angiotensin II receptor blockers or nitrosamines.
Do any such notes or other documentation, including PowerPoints, exist?
A. No.
Q. Have you ever given a

presentation, seminar, or class regarding angiotensin II receptor blockers or nitrosamines?
A. No.
Q. Have you ever given any public presentation of any nature whatsoever in your career with regard to nitrosamines?
MR. GALLAGHER: Objection to the form.
THE WITNESS: No.
BY MR. SLATER:
Q. Before you were retained in this case, did you know what an angiotensin II receptor blocker was?
A. I may have heard about it just in my education or just through my general knowledge of pharmaceuticals.
Q. Is the answer, no, not that I recall?
A. Not that I recall.
Q. Before you were retained in this case -- well, we'll get to that actually.

Let's look at Number 4. Copies of any documents or articles relied upon for the opinions set forth in the report served if not listed in the report.
Do any such documents or articles exist?
A. I've provided all the relevant articles that I've relied on in this case. There may be articles or documents that I have looked at over the course of my career or education that I've incorporated into my general knowledge base. But the articles that are relevant to my opinions have been provided.
Q. And listed in the report, correct?
A. Correct.
Q. Let's go to Page 4, Request Number 5. Copies of any documents or articles reviewed in connection with the report served, whether or not listed in the report or attachments thereto.

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And I guess based on your prior answer, the question is whether or not you've produced all the documents or articles that you reviewed in connection with the report?
A. Yes, I provided those.
Q. And again, as you said in your prior answer, if there was a document or article that you reviewed and relied on, it's listed in the report, correct?
A. Correct.
Q. Let's go to Number 6. Any illustrations, PowerPoint, images, charts, tables or demonstrative exhibits that may be used by or with Dr. Britt in connection with a Daubert hearing or trial testimony in this litigation.
Do any such illustrations, PowerPoints, charts, tables or demonstrative exhibits exist?
MR. GALLAGHER: Objection to form.
THE WITNESS: No.

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BY MR. SLATER:
Q. Let's go to Number 7, on Page 5, please. Documentation of any research grant the witness has been provided to study any angiotensin II receptor blocks or nitrosamines any health effects potentially related thereto.
Have there ever been any such research grants?
A. No.
Q. Let's go to Number 8. Documentation of any research the witness has performed with regard to any angiotensin II receptor blockers or nitrosamines or health effects potentially related thereto.
Before you were retained in this litigation, have you ever performed any such research?
MR. GALLAGHER: Objection to form.
THE WITNESS: I have not performed any research as far as,

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like, bench research.
BY MR. SLATER:
Q. You said that you had never performed any bench research?
A. Right.
Q. That would mean that you never performed experiments in a lab?
A. Experiments. Correct. I have not.
Q. Why did you draw the distinction to no bench experiments? Is there something else that did exist or occur?
A. Well, I know that from correspondence that has occurred subsequent to this, that the request was made about -- something on my CV.
Q. That's the -- that's the work that you did in connection with a munitions plant?
A. Correct. Originally I read this to be research. Like, when I think of research, especially after the question about research grants, I was

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thinking of research as far as bench research goes. Yes.
Q. You've never done any bench research or experiments regarding nitrosamines, correct?
A. Correct.
Q. Before you were retained in this case, have you ever done research with regard to the health risks of nitrosamines including NDMA and NDEA? Had you ever researched that topic?
A. There was one matter that I did evaluating some toxicity data as part -- I was not a testifying expert witness. I was just evaluating the data as part of the tasks as a consultant.
Q. So you were consulting in a matter that was in litigation?
A. Can you repeat the question?
Q. Were you consulting on a matter that was in litigation?
A. Yes. I was consulting -- I was assisting another expert.
Q. Who was the other expert

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that you were assisting?
A. Dr. Robert James.
Q. Your coworker, correct?
A. Yes.
Q. Was that the munitions issue?
A. Correct.
Q. Did Dr. James serve a report in that case?
A. I do not know if he did or not.
Q. What was the nature of the work that you did to support Dr. James in the munitions plant matter he was retained in?
A. I do not recall specifically what I did. It was likely identifying relevant studies related to the toxicity of nitrosamines, NDMA, to review. I likely reviewed the documents, provided summaries of those documents, and then he would have reviewed the summaries and reviewed the literature himself to form his opinions for the case.

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Q. When did that occur?
A. I do not recall the exact date. It was, to the best of my recollection, probably 10, 15 years ago. Probably closer to --
Q. Where were you -- go ahead. I'm sorry.
A. Probably closer to 15 years ago.
Q. Where were you working at the time?
A. I would have been working at Terra, T-E-R-R-A.
Q. Who was the company that you worked with prior to ToxStrategies, correct?
A. Correct, yes.
Q. Were you provided the -- rephrase.
The documents that you would have reviewed, were those literature, from the scientific literature?
A. Can you repeat the question?
Q. You said that you reviewed

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studies regarding the toxicity of nitrosamines including NDMA, correct?
A. Yes, that's most likely what I would have done, yes.
Q. So you would have been looking at scientific articles?
A. Correct.
Q. And you would have looked at them on a computer, right?
A. Correct.
Q. And you said that you provided summaries. Would those have been electronically typed summaries on your computer that you then provided to Dr. James?
A. More than likely, yes. Unless I -- we printed off our copies.
Q. Well, even if you printed out -- you would have prepared these electronically --
A. Yes.
Q. -- as probably a Word document, right?
A. Yes, yes.

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Q. Where are those documents now? I'm talking the literature that you collected and the summaries of that literature that you prepared for Dr. James.
A. I do not know what those documents are. We've been through many iterations and computers and computer types, Microsoft versus Mac and back and forth. A lot of the older documents, not for that case, but for other cases, I'm not even able to access, if I can find them. So I'm not sure where those documents are.
Q. Did you make an effort to locate those documents?
A. I did.
Q. What effort did you make?
A. I looked on my files that I have access to.
Q. Did you have backup systems so that if you had documents on your computer, they would be backed up in some other location?

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MR. GALLAGHER: Objection to form.
THE WITNESS: We did have backups, but after a certain period of time. Especially that far back when we switched from whatever the older Mac system was when it went to Word, a lot of my documents were lost.
So if I could find them, I don't know if they would even be readable. I looked for it. And I couldn't find it. So there were backups though.
BY MR. SLATER:
Q. Who was the client in that matter that you and Dr. James were working for?
A. I do not recall.
Q. Have you ever -- have you -- rephrase.
Is that the only munitions plant that you've ever done work in connection with in your career?

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A. I've -- well, munitions. I guess I've done some work, like, with nerve gases, but I don't think that really is consistent -- or would be consistent with munitions. But yeah, that's the only REX type.
Q. But you don't remember who the client was for the sole munitions plant matter that you ever did?
A. No.
MR. GALLAGHER: Objection to form.
THE WITNESS: No, I do not recall, mostly because I would not have been directly interacting with the client.
BY MR. SLATER:
Q. Did you speak to Dr. James to see if he could locate the materials in connection with that munitions matter?
MR. GALLAGHER: Objection to form.
THE WITNESS: No, I did not. I know just in past conversations

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with him, that he had lost all of his files in the past year or two.
So he relies on me for his files. I did not speak to him this week when this came up. He's at a funeral this week.
BY MR. SLATER:
Q. Did you say Dr. James lost all his files in the past year or two?
A. Yes.
Q. How did that happen?
A. I do not know.
Q. Do you work with Dr. James?
A. Yes, on occasion. He's in semi-retirement. He lives in Idaho now.
Q. When he left -- well, rephrase.
Is he still employed by ToxStrategies?
A. Yes. He still does consulting work for ToxStrategies. It's like a consulting type arrangement, I believe. I'm not 100 percent sure. But, yes, he still does do work for

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ToxStrategies.
Q. You said there were times when the computer systems changed over. Did you make sure that you migrated whatever information was on the existing system --
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. -- to the new system?
A. I was not responsible for that.
Q. Well, was somebody? I assume you wouldn't want to lose data when you switched computer systems, that your company would have made a concerted effort to make sure everything was saved and migrated, right?
A. I was not responsible for the computer upgrades or other people's computers or data movement or migration or when somebody gets a new computer. I'm not responsible for -- for that.
Q. Do you know who the lawyers

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were involved in the munitions plant matter?
A. Pardon me? Excuse me? Repeat the question.
Q. Do you know who the lawyers were who were involved with the munitions plant matter?
A. I do not.
Q. Do you know where the case was filed?
A. It was in Utah.
Q. Do you know what the outcome of the case was?
A. I remember it did go to trial.
Q. Is it in state or federal court? Do you know?
A. I do not know.
Q. Did you attend the trial?
A. No.
Q. Did Dr. James testify at the trial?
A. Yes.
Q. Who was -- rephrase.

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What was the involvement of your client -- if you don't remember the name of the client, what was the involvement of the client? Was it the owner of the munitions plant, was it someone who was harmed at the munitions plant? Who were you working on behalf of?
MR. GALLAGHER: Objection to form.
THE WITNESS: I don't remember.
BY MR. SLATER:
Q. Well, was your goal to minimize the risks from whatever chemicals or substances were in the munitions plant? Was that the assignment for your company?
MR. GALLAGHER: Objection to form. Objection to form.
THE WITNESS: No.
BY MR. SLATER:
Q. Do you know what the -- rephrase.

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Do you know what your company was retained for? Do you have an understanding of why you were retained?
MR. GALLAGHER: Objection to form.
THE WITNESS: I don't recall the specific reason why we were retained for that particular case. It was likely just to evaluate the data, subject data, toxicity, and reach a conclusion as to whether or not there was any increased risk or harm or just -- specifically, I don't remember the case.
BY MR. SLATER:
Q. With regard to nitrosamines in that case, was NDMA the nitrosamine that you evaluated?
A. I believe it was one of the chemicals. And I only say that because it's on my CV. I did go back and look at my older CVs. And it was on my older CVs dating back to 2012 or 2011, so.

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Q. So is the answer yes, NDMA was the nitrosamine?
A. Yes. Yes.
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Do you recall what studies you looked at at the time?
A. I do not.
Q. Do you recall what your summaries of the literature you reviewed stated?
A. I do not.
MR. SLATER: I'm going to move on to a new subject for now. But we're going to reserve all our rights with regard to this subject to request further documents or information on the subject of the work done on this munitions plant matter.
MR. GALLAGHER: Yeah, Adam, we've responded to this.

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MR. SLATER: Well, I'm just stating for the record that I reserve my right to make other requests, now that I have some testimony. But we'll maybe come back to it. Maybe we won't.

BY MR. SLATER:

Q. Other than the matter regarding the munitions plant about 15 years ago where you assisted Dr. James, have you ever in your career before being retained in this case done any research with regard to nitrosamines or NDMA or NDEA in particular?

A. Can you repeat the question?

Q. Other than the munitions plant matter that we've just spoken about, is there ever a time in your career where you've researched nitrosamines or NDMA or NDEA in particular before being retained in this matter?

MR. GALLAGHER: Objection to form.

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THE WITNESS: I do not recall being asked.

BY MR. SLATER:

Q. Did you say that you don't recall?

A. -- recall --

Q. Nothing that you can remember as you sit here now, right?

A. Can you repeat the question?

Q. Nothing that you can think of as you sit here right now, correct?

A. Correct.

Q. One other question going back to the report on the munitions. Was Dr. Guzelian involved as well?

A. I do not recall. He may have been. But I can't recall specifically.

Q. Did you make any effort to speak to Dr. Guzelian about the -- your effort to find documents regarding the munitions plant matter?

A. No.

MR. GALLAGHER: Objection to form.

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THE WITNESS: No, I did not.

BY MR. SLATER:

Q. Does he work with your company or is he separately employed?

A. He's separately employed.

Q. Number 9, I think we can skip because that would not be applicable to you because you don't have hospital privileges anywhere, correct?

A. Can you repeat your question?

Q. I'm looking at the deposition notice now. Request Number 9, on Page 5.

A. Okay.

Q. I'm assuming that you have no appointments or privileges with any hospital or academic institution; is that correct?

A. That's correct.

Q. Let's go to the next page, Page 6, Request Number 10.

Number 10 requested any

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documents or other communications the witness has received from any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug outside of information provided by counsel who retained the witness.

Do any such documents or communications exist?

A. No.

Q. Who are you retained by?

A. Duane Morris.

Q. So no other lawyer from any other law firm has provided you any other document or other substantive communications that you --

A. Let me --

MR. GALLAGHER: Objection to form.

MR. SLATER: I hadn't finished the question.

THE WITNESS: I was retained by Duane Morris, but there's co-defendants.

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So legal -- I guess legally maybe I didn't respond to your question correctly. I guess they all retained me.
BY MR. SLATER:
Q. Other than Duane Morris, did any lawyers from any other law firm provide you documents or information that you considered in writing your report?
A. Yes. Yes. And I am working with them also. And they did provide documents and those were provided to you.
Q. Are they all listed in the report?
A. Pardon me? Can you explain?
Q. Are they all listed in your report?
A. Yes, they are.
Q. Number 11 --
A. May I add a caveat to that. Unless it was something that was received after my report it wouldn't be listed, but it would have still been sent as -- in response to this.

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Q. Well, we're going to get to it. But I have one report from you dated August 2, 2021. That's your only report in this case, right?
A. That's correct.
Q. Number 11 requests any communications from the witness to any person or entity with regard to nitrosamine impurities in any angiotensin II receptor blocker or other drug outside of communications with counsel who retained the witness.
Do any such communications exist?
A. No.
Q. Number 12, requests any textbook referenced by the witness in forming her opinions. Is there any such textbook?
A. Any textbook or document should be included in my -- what was sent to you all, so.
Q. Did you rely on any textbook in forming your opinions?

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A. I know there was one textbook. And I did send that to you.
Q. Which textbook is that?
A. Everything that has been sent, yes, everything has been sent.
Q. What was the one textbook?
A. It was a book chapter out of Wilson and Crouch. I was sent that textbook. It was on risks, general risks.
Q. General risks of what?
MR. GALLAGHER: Objection to form.
THE WITNESS: Various jobs, work exposure factors, exposures that we have in mind.
BY MR. SLATER:
Q. Anything specific in that textbook to nitrosamines, NDMA or NDEA?
A. Not that I recall.
Q. You can put that aside.
Let me ask you, Doctor, do you have your report, your complete report with all the exhibits and

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attachments, electronically only or do you have a hard copy with you?
A. I have an electronic copy.
Q. All right.
MR. SLATER: All right. Let's put the report up on the screen and mark that as Exhibit 3 please.
(Document Marked for identification as Exhibit Britt-3.)
BY MR. SLATER:
Q. On the screen as Exhibit 3 is a document titled "Expert report of Janice K. Britt, Ph.D." And it's dated August 2, 2021.
Is that your report in this case?
A. Yes. Let me pull it up real quick. Hit refresh right? Yes, correct.
Q. If I were to go to reports that you've written in other cases, would I find the same or very similar language

in reports in other matters as some of the sections of this report?

MR. GALLAGHER: Objection to form.

THE WITNESS: The general format of my reports is very similar.

BY MR. SLATER:

Q. What do you mean by that?

A. Phrasing of the -- my understanding of the case, my background, my qualifications, methods, my opinions, and if I have any appendices. So that's sort of the general format that I use in all my reports. So they probably look similar. The body will look different, because it's different chemicals, different exposures, different issues.

Q. Are there any sections of the substantive content of this report, that if I went to reports you wrote in other cases, that I would find the same or very similar language?

MR. GALLAGHER: Objection to

form.

BY MR. SLATER:

Q. What I'm getting at is this -- what I'm getting at is this: There are some general discussions about risks and animal studies and things like that.

Is that information found in other reports you've written as well, where you basically have this section that you talk about these issues where you've used that in multiple reports over the years?

MR. GALLAGHER: Objection to form.

THE WITNESS: Yeah, some of the language -- some of the risk numbers have been used. You know, some of the language has been used in other reports. I update it. I revise it, you know, as new information comes out.

So yes. In some of the reports, not in all. If it's

relevant, it may be included.

BY MR. SLATER:

Q. So if I understand correctly, this entire report was not written specifically for this matter. There are parts of this report that you took from work product that you had from the past and adapted it to use in this report.

Do I understand correctly?

MR. GALLAGHER: Objection to form.

THE WITNESS: That would only apply to some of the, just generic background risk information. And it can -- I would have updated it, and I would have adapted it to the case-specific information here.

BY MR. SLATER:

Q. Which parts of the report contain what you've termed the generic background risk information?

A. It would be the background

cancer risk that we all face, exposures to radiation, exposures to carcinogens in our diet, things like that, some of the -- or kind of the back end of the report. And I -- of course, I updated it and there's information that's more specific to issues here, like the overall age of the population, prevalence of hypertension. So it's -- some of it's similar, but then again it's updated and it's adapted.

Q. I'm going to come back to just a few basic questions. I think I might have gotten myself sidetracked.

The report that's Exhibit 3, that is your report in this case, correct?

A. Yes. This is the report in my case, yeah, in this case, yes.

Q. When you signed this report, did you carefully read it to make sure that it accurately stated everything that you wanted to communicate in the report?

A. Yes.

Q. You understood in writing this report, that you were required to set forth the opinions that you had reached, correct?
A. Correct.
Q. Did you do so? Does this report contain your opinions?
A. Yes.
Q. We've already gone over this, but just to confirm, are all the materials that you actually relied on in forming those opinions listed in the report and the list of references attached?
A. Yes.
Q. In the course of the report, you go through various facts and you discuss some facts in some detail. Does the report contain those facts that you believed were most important to you in forming your opinions?
A. Can you repeat the question?
Q. Sure. Does the report contain and discuss those facts that were

most important to you in forming your opinions?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah, so, I mean, I considered other information, you know, what was important, you know, went into my report, you know, the most, I guess, key elements that were relevant to this case, so yes.
BY MR. SLATER:
Q. The key facts that you felt were most relevant to this case and were the basis of your opinions, they are set forth in this report, correct?
A. Correct. Like, for example, if there was, especially like an understanding of the case. I'm assuming that's what you're talking about. I was -- you know, I didn't put in every single, solitary detail about all the recall information.
I summarized it, you know,

to be succinct and complete. So let me know if that's not what your -- what you're talking about.
Q. I'm asking about all the facts in the report. You -- well, rephrase. I'll ask it differently.
Throughout the report, there were various facts you cited. And what I just want to make sure of is that those facts that were most important to you in forming your opinions are set forth in the report, so I can understand what are the facts you're relying on and drawing your opinions based upon?
A. Yes, yes, yes.
Q. We'll get to it. You've been an expert in other litigation, correct? This is not your first time?
A. Correct.
Q. Do you agree that it's important for an expert witness in a case such as this to be objective?
A. Yes.
Q. Do you agree that it's

important for an expert in a case like this to have no bias impacting her or his opinions?
A. Yes.
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes.
BY MR. SLATER:
Q. Do you agree that in your work in this case, it was important for you to consider the important facts and the important studies and literature that related to the subject that you were opining on?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you repeat the question?
BY MR. SLATER:
Q. Sure. Do you agree that, to the extent there were studies or literature that would be significant to the subject you gave your opinions on, that you needed to consider those studies

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or literature?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes, I agree that it's important to analyze the literature. And -- yes, I agree.
BY MR. SLATER:
Q. For example, if there was something that was important factually that was in the possession of the attorneys in this case who are on the defense side, that might have impacted your opinions, and you would want to see that, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you repeat the first -- or can you just repeat that question?
BY MR. SLATER:
Q. Sure. You were retained by the lawyers at Duane Morris, but you've made clear that you were working on behalf of all the lawyers on the defense

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side, and you gave us the names of a bunch of them that you spoke with, correct?
A. Correct.
Q. To the extent that they were aware of materials that were exchanged in the course of this litigation, and those materials could have been significant to your opinions, you would have wanted to see those materials, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. For example, if one of the defendants or more of the defendants had retained or got an opinion from a toxicologist about the health risks of the nitrosamine impurities, you would want to see that, right, before forming your opinion in this case, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: If it was --

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if it was for this -- if it was relevant for this case and it was done for this matter, yes.
BY MR. SLATER:
Q. Did you see any documents -- well, rephrase. Let me ask it differently.
Were you provided any documents with regard to an evaluation of the health risks of the nitrosamine impurities that was performed by any toxicologist that was either employed by or consulting for any of the manufacturers in this case?
A. Yes. I believe there was some outside or expert reports that were provided.
Q. And to the extent they were provided to you, they were listed in your report, right?
A. Correct.
Q. If there were other documents that the lawyers had with regard to that report or reports you were

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provided, meaning, for example, e-mails where the toxicologist who wrote the report was talking in more detail about his or her opinions, you would have wanted to see that as well, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct, if there were -- if there were relevant e-mails.
BY MR. SLATER:
Q. And ultimately what I'm driving at here is, if you were -- rephrase.
What I'm driving at is that you as an expert want to review anything that's relevant and significant to the subject that you're giving an opinion on, right? You don't want to later find out that there's some gap in your knowledge that could impact your opinions, right?
A. That's correct.
MR. GALLAGHER: Object to form.

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THE WITNESS: I mean, but I did review all the materials that I received. And these other reports are these individuals' opinions. But ultimately I came to my own opinions. But I did review those other outside reports.

BY MR. SLATER:

Q. Your report has a few exhibits, and what I'd like to do first is go to Exhibit A to your report, if we could, which is part of Exhibit 3, obviously. But the report itself has an Exhibit A, which I believe is your CV; is that correct?

A. Did you say this is part of Exhibit 3?

Q. It should be, right? I'm not looking to --

MR. SLATER: Chris, I don't want to do a separate -- well, actually, it's fine. You know what, let's go ahead. You can

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mark Exhibit A to Dr. Britt's August 2, 2021 report as Exhibit 4.

So it will be part of Exhibit 3, and it will also be separately marked as Exhibit 4.

MR. GALLAGHER: It is not part of Exhibit 3, because they were produced as separate documents.

MR. SLATER: Ah, thank you for clarifying that.

MR. GALLAGHER: Just to be clear for the record. Yeah.

(Document marked for identification as Exhibit Britt-4.)

BY MR. SLATER:

Q. All right. So we're going to look at Exhibit 4 now, which is Exhibit A to your report.

MR. SLATER: I just want to make something clear for the record, because this isn't how I

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wanted this done. I want Exhibit 3 -- and we're going to do this today so we can confirm it for everybody, to contain everything that was -- I want it to include the exhibits, A, B, and C which are the exhibits to the report.

I'm going to want those to be attached to complete the report with all the exhibits. Okay?

We don't have to do it now, but we'll want to do that later.

MR. GALLAGHER: Yeah, you're welcome to mark the exhibits as you wish.

MR. SLATER: No, I was actually not saying that to you, I was letting Chris know.

MR. GALLAGHER: Okay.

MR. SLATER: But thank you. Thank you.

BY MR. SLATER:

Q. So we're now looking at

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Exhibit 4, which is Exhibit A to your report. Is that your CV?

A. Yes, it is.

Q. Is that your most up-to-date CV. It has a date of April 2021 on it?

A. I believe I have a -- maybe a June or July 2021 CV.

Q. Do you know why that wasn't provided to us?

A. I do not. It was just updated. We can look and see. Maybe it's September. It's -- my editor was taking a while to update it. It's -- my newer one just contains probably just a couple more publications or abstracts. That would be the only significant difference.

MR. SLATER: Would it be possible at a break just to send that over to us so we can just mark it and make sure that we can then just identify anything that's in addition to what we have here?

MR. GALLAGHER: Yep, we'll

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take that under advisement at a break.

MR. SLATER: Thank you.

BY MR. SLATER:

Q. This says that you work at ToxStrategies, and your title is managing scientist; is that correct?

A. Correct.

Q. What is ToxStrategies?

A. It's a consulting firm that provides services in areas of toxicology, risk assessment. We have a variety of different types of scientists that are employed there, and we do different types of work. Basically, we're mostly -- mostly toxicologists.

Q. How many toxicologists are employed by ToxStrategies?

A. I'm not sure exactly. Approximately -- maybe approximately 20, 15, 20.

Q. You said there are -- rephrase.

Are there any other --

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rephrase.

Are there any scientists or employees who have -- who are not toxicologists but are actually -- who specialize in some other field?

A. We have engineers, and I believe we have some statisticians, biostatisticians. So we have individuals who have degrees in non-toxicology.

Q. Were you the only person from ToxStrategies that worked on this matter, or did anybody else work on it?

A. I'm the only person that worked on this report, aside from I had someone who pulled a few papers for me in our library, I think Christine. And I had an individual check my risk numbers, QC my risk numbers.

Q. What does that mean?

A. For my risk calculations, I just wanted to make sure there was no errors. So I had them check my numbers.

Q. Who checked your numbers?

A. That would have been Jon

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Urban. He's also --

Q. What's his specialty?

A. He's a Ph.D. toxicologist.

And an editor that puts periods in and makes sure that my sentences are complete.

Q. Who was the editor?

A. Rick Nelson.

Q. You said Rick Nielsen?

A. Nelson, N-E-L-S-O-N.

Q. I didn't know if you had the guitar player for the -- lead guitar for Cheap Trick working with you now.

A. Well, you know.

Q. On the first page of your CV, there's a section that says professional profile, which I assume is a general summary of the work that you do, correct?

A. Correct. Past work and present work, sort of a mixture.

Q. You are a toxicologist, correct?

A. That's correct.

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Q. You are not a physician. We know that, right? Is that correct?

A. That is correct. I have a Ph.D. in toxicology.

Q. Are you an epidemiologist?

A. No, I'm not an epidemiologist, but I have had courses in epidemiology. And as part of being a toxicologist, we do evaluate epi studies, hemo studies, occupational studies.

So I do have familiarity with epidemiologic literature and some of the shortcomings, but I'm not a -- I do not have a Ph.D. in epidemiology.

Q. First question, you are not an epidemiologist, right?

A. No.

Q. You don't hold yourself out as an expert in epidemiology, do you?

A. Correct. I do not.

Q. And I think I saw something in your report about the fact that even though you discuss some epidemiologic literature, you're aware that there are

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other defense experts who specialize in that field. You wrote something to that effect in your report, right?
A. Correct.
Q. And do I understand that to mean that you discussed the epidemiology that you talk about in your report, but you really would defer to the epidemiologists that were retained by the defense with regard to their evaluation and analysis of the epidemiologic literature? Is that correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you repeat the question?
BY MR. SLATER:
Q. Are you deferring to the defense experts who are epidemiologists with regard to the analysis and import of the epidemiology studies that you mentioned? Because I think you said something about that in your report, that there were more qualified experts who

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actually specialize in that field. So I just want to know if I understood that correctly?
A. Like I just said, I'm not -- I'm not the epidemiologist in this case, and I don't have a Ph.D. in epidemiology. And I can review the papers. But on specific information or to file opinions on papers, I would defer to the other experts in this case.
Q. And your report specifically referred to the defense expert epidemiologists. Why didn't you also defer to the plaintiff expert epidemiologists?
MR. GALLAGHER: Objection to form.
THE WITNESS: I -- ultimately I agreed more with the methodology of the defense expert.
BY MR. SLATER:
Q. You thought that the defense expert epidemiologist used a different methodology than the plaintiff expert

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epidemiologist?
A. The methodology, the type of methodology.
Q. When you say the type of methodology, what do you mean by that?
A. Just the methodology he used, the literature search, the consideration of confounders, just overall.
Q. Well, I interpret methodology to mean the approach that the expert took in terms of what was reviewed and considered as part of the overall analysis. Did you think that the epidemiologists on the plaintiff and defense side followed different methodologies?
MR. GALLAGHER: Objection to form.
THE WITNESS: I don't recall --
BY MR. SLATER:
Q. Or is that something -- is that something that you're not sure of?

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A. I don't recall the specific methodology. But I recall reading the expert's report and I agreed with their methodology.
Q. Did you read the plaintiff expert epidemiologist's report?
A. Yes, I did.
Q. Did you read it completely, all the pages?
A. Yes, I did.
Q. When you say that you agreed with the defense expert methodology more than you agreed with the plaintiff expert methodology, do you mean to say that you agree with the conclusions drawn by the expert on the defense side? Is that what you're saying?
MR. GALLAGHER: Objection to form.
THE WITNESS: No, just the overall approach and the methodology used.
BY MR. SLATER:
Q. What was different about the

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overall approach and methodology that made you favor the defense expert versus the plaintiff expert? Do you recall?
A. I do not recall the specific examples of the differences between the two.
Q. In the professional profile on Page 1 of your CV, about half to two-thirds of the way down, where you have a list of all the specific compounds that you've worked with, there is a listing of n-nitrosodimethylamine, NDMA.
Do you see that?
A. Yes.
Q. Is that listed in connection with the munitions plant matter in Utah that we talked about earlier in the deposition?
A. Yes.
Q. Because that's the only other matter or time that you've actually worked with or evaluated, I should say, NDMA, correct?
A. Correct.

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Q. If you could, could you please go to the second page of your CV. At the very top, there is some societies that you are a member of. I'd like to walk through those. The Society of Toxicology, what is that?
A. That's the main society of toxicologists. Membership is probably about 10,000 individuals. Just what toxicologists join, that's the main -- our main society, just like the American Bar Association is for lawyers.
It's where -- we have a journal. We have newsletters. It's just the main society, and you have to be -- you have to have letters of recommendation. You have to have a certain number of years of experience, and there's different degrees of membership. So I'm one of them. So it's basically -- it's our society.
Q. Does that society have meetings?
A. Yes, it does.

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Q. Who sponsors those meetings?
A. I do not know who.
Q. Have you ever attended those meetings?
A. Yes, I have.
Q. Would people from -- rephrase.
Have various industry groups, for example, sponsored booths or dinners or presentations talking about industry groups, maybe in the pesticide area or employers of workers in occupational settings, that sort of thing? Do they sponsor parts of those meetings?
A. I don't know about that. I don't have knowledge of that.
Q. What is the Society For Risk Analysis?
A. It's -- it's a smaller society. They do have meetings every year, and they have a journal. It's more for risk assessment. It's for people who do -- you know, analyze risks of exposure

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to radon and cancer or -- you know, different types -- so it's more -- it's more statistical analysis and risk analysis. It's -- there is some toxicology involved, but it's more for a risk assessor type.
Q. Going back to the Society of Toxicology. Do you know whether or not there can be corporate memberships as well as individuals that can be members of that society?
A. I'm not aware of that.
Q. Do you know for the Society of Risk Analysis, are there corporate members?
A. I do not know.
Q. What is the American Conference of Governmental Industrial Hygienists?
A. It's an organization for industrial hygienists. I'm not an industrial hygienist, but I have an associate membership. It's the organization that has recommended levels

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of different compounds, radiation, vibration, noise for the workplace. Similar to OSHA PELs or the NIOSH values. They do have meetings where they set these levels. So I'm just a member in that.

Q. What is EUROTOX?

A. That's the European -- sort of like the European toxicology society. So I'm a member of that.

Q. Do you know if any of these societies that we just talked about are, or were created by, or are sponsored by chemical manufacturers?

A. I do not know.

Q. Am I correct that you're limiting your opinions in this case to opinions formed in the field of toxicology?

MR. GALLAGHER: Objection to form.

THE WITNESS: Yes, I am, with the caveat that if I evaluated, you know, like I said,

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an epi paper or a human health paper that also falls within the realm of toxicology, because we also evaluate epi papers. But I am a toxicologist. That is my field.

BY MR. SLATER:

Q. For example, you're not offering medical opinions, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: No. I'm not offering medical opinions.

BY MR. SLATER:

Q. That would be outside your expertise, correct?

A. That's correct.

Q. I'm looking now at Page 3 of your report which has a heading, professional experience.

Do you see that?

MR. GALLAGHER: Do you mean -- is it the report or the CV?

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MR. SLATER: Did I say report?

MR. GALLAGHER: Yes.

MR. SLATER: Just making sure you're awake, Patrick.

BY MR. SLATER:

Q. Looking now at Page 3 of your CV, there's a heading, professional experience.

Do you see that?

A. Yes.

Q. What is that communicating to us as we read this?

A. Those are just examples of different types of chemicals or occupational exposures or consumer products or pharmaceutical products that I've evaluated and the types of evaluations that I've done with those types of products.

Q. Does this include both litigated matters and matters in which you were asked to consult for a company and provide your input?

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A. Yes, it's a mixture. It's a mixture of litigation, as well as some of the pharmaceutical work I do, pet food, consumer products. You know, it's just a mixture of everything that I do, all of my professional experience.

Q. There is a subsection that says "Chemical-Specific Toxicity Assessments."

Do you see that?

A. Yes.

Q. With regard to that section of this CV, is every single example provided there work that you performed on behalf of a manufacturer of some substance or product?

A. Can you repeat your question?

Q. Let me tell you what I'm trying to get at. That probably wasn't the best to get at it. I'll ask it differently.

There's a subheading, "Chemical-Specific Toxicity Assessments."

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Do any of the examples provided relate to a matter where you were retained on behalf of a plaintiff, somebody who claims to have been harmed due to some toxic substance? Has it ever -- do any of these examples cover such a situation?

MR. GALLAGHER: Objection to form.

THE WITNESS: Do you mean where I was retained as an expert witness?

BY MR. SLATER:

Q. Expert witness or as a consultant on behalf of a plaintiff, someone who was harmed or alleging a harm due to exposure to a substance?

MR. GALLAGHER: Objection to form.

THE WITNESS: Some of these were just general evaluations. Some of them were defense. I don't know if any specifically were plaintiff, if that makes

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sense.

BY MR. SLATER:

Q. What I'm trying to understand is whether any of the examples that you provide under the heading "Chemical-Specific Toxicity Assessments" related to a matter where you were retained to be a consultant or an expert on behalf of a person who claimed to have been harmed due to a toxic or potentially toxic substance?

A. No, I do not believe so.

Q. Have you ever been retained in your career on behalf of a plaintiff in a litigation who was claiming to have been harmed due to exposure to a toxic substance?

MR. GALLAGHER: Objection to form.

THE WITNESS: As an expert?

BY MR. SLATER:

Q. Right.

A. No. I have not been retained as an expert.

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Q. So every time you've ever been in any litigated matter in your career, it's been on behalf of the defense, correct?

A. State that one more time or please repeat it.

Q. Sure. Am I correct that every single time in your career that you've been retained in a litigated matter, it's been on behalf of the defense?

A. Yes. All my retentions have been for the defense. I have evaluated cases with plaintiffs' lawyers and worked for plaintiffs. But all my retentions have been defense.

Q. What do you mean that you've evaluated matters for plaintiff lawyers?

A. Like lawyers, I mean -- just through ToxStrategies we get requests for evaluations. And so I evaluate those, and I look at all the evidence, the literature, the complaint, the exposure, the medical records, whatever information

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that I request. And it's provided to me.

And then I come to a conclusion, or a preliminary conclusion. And then I make that -- I discuss it with a potential client. So it's just never worked out that any of those have been plaintiffs so far.

I know that we had one that I wasn't the expert. There was a plaintiff, one or two, but I haven't been the expert.

Q. You're saying there's one or two examples you can recall where a plaintiff lawyer came to your firm and asked if your firm could look at a situation and potentially be an expert?

A. I mean, there's --

MR. GALLAGHER: Objection to form.

THE WITNESS: There have been several that have come to us, and that I've looked at, and, you know, we've talked about it. And I don't know what happened to the

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disposition of the case.
There's been -- over the years, I mean, we have done plaintiffs. I mean, I can recall more recently that Dr. James -- so it does happen. It's not very common though.
BY MR. SLATER:
Q. Any time a plaintiff attorney has come to your company to see if your company could support their case that a toxic substance harmed an individual, you've told the lawyer, "We can't help you. We can't give that opinion. You need to go find somebody else." Is that a fair summary?
MR. GALLAGHER: Objection to form.
THE WITNESS: No, no. I always talk to them. I get the information. I look at it the same way. I look at everything with -- the same way that I look at all the same information and

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request medical records, depositions, you know, any exposure data.
And I make an assessment. It's I -- it's all the same. It's all done the same way, regardless of who is --
BY MR. SLATER:
Q. But what I'm getting at is -- what I'm getting at is, in all those matters you've ultimately told the plaintiff lawyer, "I'm sorry. I can't help you. I can't give you the opinion, that you're -- that you need in order to advance this case. You need to find someone else."
Correct?
MR. GALLAGHER: Objection to form. Objection to form. Asked and answered.
THE WITNESS: Like I said, I tell them the opinion that I have. And then usually I either -- usually don't hear back from them

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or --
So I don't know what happens with the case, the disposition with the other side.
I don't understand the inner workings of law firms or employers or what they do with that information.
BY MR. SLATER:
Q. I think we're overcomplicating this. This is what I'm asking.
In the instances over the years where a plaintiff lawyer has come to your firm, provided information and documents to see if you could support their case as a plaintiff, once you've looked at the materials, you've said no, I can't support your case, and they've had to go elsewhere; is that correct?
MR. GALLAGHER: Objection to form. Asked and answered.
THE WITNESS: I don't say that. I give them my opinion of

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the case.
BY MR. SLATER:
Q. If your opinion had been -- if your opinion had been well, yes, I think this toxic exposure caused your client's harm, presumably you'd be retained. But you're telling me in every instance where a plaintiff has come to you, you've said, "I cannot support the position that the toxic substance or the toxic exposure at issue harmed your client."
That's -- I'm just trying to get to the bottom line. That's been the ultimate outcome of those matters, right?
MR. GALLAGHER: Objection to form. Mischaracterizes testimony. Asked and answered. And when you get a chance, Adam, we've been going about an hour and-a-half now. But go ahead.
BY MR. SLATER:
Q. You can answer.
A. Correct, I mean, I give them

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my opinion and if -- and sometimes we're retained, and sometimes we're not.
Q. Have you ever given the opinion in any litigated matter that a plaintiff was exposed to a toxic substance that was at issue in that case, and that it caused harm to that plaintiff?
A. Can you repeat that?
Q. Sure.
Have you ever given the opinion in your career that a plaintiff who alleged injury due to exposure to a toxic substance, was actually harmed by that substance?
MR. GALLAGHER: Objection to form.
THE WITNESS: I have not been the expert in a case where I had that opinion.
MR. SLATER: If you want to take a break now, we can do it. Let's go off the record.
THE VIDEOGRAPHER: The time

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right now is 10:40 a.m. We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time is 10:56 a.m. We're back on the record.
BY MR. SLATER:
Q. I need to go over a couple of things that I forgot to ask you about a little earlier.
Do you hold yourself out as a regulatory expert?
A. Can you repeat that?
Q. Sure. Do you hold yourself out as a regulatory expert?
MR. GALLAGHER: Objection to form.
THE WITNESS: I am familiar with some regulations. But you'd have to be more specific.
BY MR. SLATER:
Q. In terms of the expert -- rephrase.
In terms of your expert

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qualifications, are you putting yourself out as an expert in the field of regulatory matters -- rephrase.
Let me ask it differently.
Do you hold yourself out as a regulatory expert, where people can come to you and you can give them regulatory expertise where you have a full understanding of the regulatory structure, the regulatory world, where you specialize in that field?
MR. GALLAGHER: Objection to form.
THE WITNESS: No. That's not my primary area of expertise. So no, that's not my -- that's not what I was asked to provide in this case.
BY MR. SLATER:
Q. Sorry. I was writing notes, and I realize that I couldn't read any of them, I had to rewrite my own notes.
Looking at your CV back on Page 3. At the bottom of that page

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there's a matter where you say that you did review of toxicity of glyphosate.
Who was that review done for?
A. I do not recall who that would have been for. That would have been several years ago. I do not recall who that would have been done for.
Q. Was it the manufacturer of a product that contained glyphosate?
A. I do not recall.
Q. Did you reach an opinion as to whether or not glyphosate is toxic to humans?
MR. GALLAGHER: Objection to form. I'll caution you to the extent any of the substance of your opinions is confidential, I caution you not to breach confidentiality agreements.
THE WITNESS: Like I said, I don't recall. I also don't recall if I was -- in this specific instance if I was working for -- I

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definitely was not an expert or a named expert in this matter. I don't know if I was assisting another consultant or if I was -- I don't even remember the specifics of this, what this task was for.

I would have likely looked at, you know, exactly what it said. I would have looked at the toxicity, looked at regulatory information and then either provided that to whoever requested me to do that. That's the extent of my knowledge at this time.

BY MR. SLATER:

Q. Could you look at Page 4, please, of your CV. The third entry from the top says, "Evaluation of potential carcinogenicity of take-home asbestos exposure. Evaluation of the animal and epidemiological asbestos literature brake worker studies for mesothelioma."

Do you see that?

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A. Yes.

Q. Who did you do that for, that assignment?

A. I was assisting another consultant for that. I was not an expert in that case.

Q. Who was the client?

A. That would be confidential.

Q. Was it the employer of brake workers --

A. No.

Q. -- without telling me who it was?

A. No, it was not.

Q. Did you reach a conclusion as to whether or not take-home asbestos exposure was carcinogenic to humans?

MR. GALLAGHER: Objection to form. And again, to the extent the substance --

MR. SLATER: We don't know who the client was. So I'm not really understanding what these objections are.

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I'm allowed to understand the opinions that she's formed based on the analysis over her career.

THE WITNESS: Since I was performing tasks for -- that I was given, I would have summarized information but it would have been ultimately the expert that would have formed the opinions, not me.

BY MR. SLATER:

Q. Do you recall what your understanding of the literature was as to whether or not take-home asbestos exposure can be carcinogenic to humans?

MR. GALLAGHER: Objection to form.

THE WITNESS: In the context of this specific case or in general?

BY MR. SLATER:

Q. In the context of what is listed there, the third entry on this page that we are talking about.

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A. I mean, again, this is a confidential matter. So I'm not sure if I should be discussing this specifically.

MR. GALLAGHER: If it's confidential, you should not be disclosing.

THE WITNESS: I think this is confidential, so...

BY MR. SLATER:

Q. Let's go four further down, "Evaluation of the carcinogenicity of chrysotile asbestos."

Who was that assignment for?

A. I do not recall who that was for. That was also for another expert. That was probably 15 to 20 years ago. I would not -- I was not aware -- I do not know who the client was for that.

Q. What was the conclusion that you reached based on your evaluation of the carcinogenicity of chrysotile asbestos. Did you conclude that it's carcinogenic to humans?

A. Again, I would have just

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been pulling background information on exposure to fibers, various sort of state-of-the-art issues on what was known when. And then I would have given that information to the expert to allow them to draw their own conclusions. I don't remember if I drew conclusions at the time.

Q. Going down another four or five. There's, "Effects of tire-derived fuel burn. Evaluated the adverse effects of inhalation exposure to various compounds, including mercury and zinc and particulate matter from a tire-derived fuel test burn."

Do you know who you were retained by to do that evaluation?

A. I do not. I do not recall who the client was for that. It was more of a consulting matter for the client. I do not remember that there was a particular matter. I just remember that we looked at the literature and just kind of provided information on -- to what the

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effects would be.

Q. Going further down, there's one that says, "Toxicity of carbon monoxide. Reviewed the carbon monoxide toxicity literature, in particular the literature concerned with the neuropsychological effects of exposure."

Was that part of a defense of a litigated matter?

A. I believe that probably encompasses just my general experience that I've had with carbon monoxide over the years, not one particular experience or one particular matter. So that's sort of a general statement, my general experience.

Q. You're saying you don't -- I'm sorry. I didn't mean to talk over you. You're saying it's a general?

A. No. They're -- general -- sorry.

General experience that I have, there has been issues, you know, in my career where I've been asked to look

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at carbon monoxide toxicity.

Q. Well, this says not in general, it says in particular the literature concerned with the neuropsychological effects of exposure.

So I was assuming this was a matter where somebody claimed to have been exposed to CO2 and that it caused neuropsychological harm?

A. Well, there's --

MR. GALLAGHER: Objection to form.

THE WITNESS: Correct.

MR. GALLAGHER: Objection to form.

THE WITNESS: Correct.

That's usually what -- when you've got carbon monoxide, that's usually the effect that you're going to see.

So if I was ever asked or, whenever we look at or I look at carbon monoxide, that's usually the effect or the endpoint or

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whatever -- the most common that we look at or I look at.

When I say we, I'm thinking of toxicologists in general.

BY MR. SLATER:

Q. Am I correct -- well, we've already covered it.

Let's go now to Page 5. There is a subheading that says, "Food Additives and Flavorings?"

Do you see that?

A. Yes.

Q. At the bottom of that page it says, "Safety of farmed versus wild salmon. Evaluated the concentrations of PCB in farmed and wild salmon compared to the U.S. FDA's tolerance level."

Do you recall who you performed that evaluation for?

A. That was another matter I was assisting someone else with. I do not know who the client was, that was farmed or wild. I just know that we were asked to look at the different

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concentrations and compared them to the level -- this was an older case. I would say probably 15 years ago.
Q. This refers to PCBs. What are PCBs?
A. Those are polychlorinatedbiphenyls.
Q. Are they toxic to humans?
MR. GALLAGHER: Objection to form.
THE WITNESS: It depends on the concentration.
BY MR. SLATER:
Q. At certain concentrations, it can be toxic to humans?
A. The most common effect are -- really, the main effect seen at really high occupational levels is chloracne, which is a skin condition. It sort of looks like acne.
Q. Page 6 of your CV. There is a heading that says "Consumer and Personal Care Products."
A. Okay.

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Q. Going about two-thirds of the way down the page there is one that says, "Evaluation of the carcinogenicity of benzene, trichloroethylene and 1,1,1-trichloroethylene and brain cancer."
Who did you perform that evaluation for?
A. I do not recall the client. I believe it was -- those were components of a -- of a glue, but I do not recall the specific client.
Q. And when you say that you believe it had to do with components of a glue, it says that in the entry. Chemical testing on the glue product --
A. Okay. Yes.
Q. -- and result evaluating --
A. So, yeah.
Q. I'll read it again. This says, "Chemical testing on the glue product was conducted and results evaluated to assess other potential exposures."

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Was that chemical testing performed by you?
A. No, it was not.
Q. Was it done by --
A. It was performed -- yeah, one of the individuals at our company had industrial hygiene experience and they organized that testing. And we looked at those results and evaluated them.
Q. Do you recall what the conclusion was as to the carcinogenicity of those substances?
MR. GALLAGHER: Same caution with respect to the extent the substance is confidential.
THE WITNESS: Yeah. I mean, it's -- none of these compounds were determined to cause brain cancer in humans.
BY MR. SLATER:
Q. Is benzene a carcinogen to humans?
A. The only known cancer associated with benzene is acute

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myelogenous leukemia, but high doses, typically in worker studies.
Q. Please go to Page 7. At the bottom of the section that we've just been going through, the last entry is "General pesticide experience, evaluated the toxicity of numerous pesticides."
Do you see that entry? Right where it says, "Pharmaceutical agents and medical devices."
A. Oh, yes.
Q. There's a whole list of different pesticides there, correct?
A. Correct.
Q. Are any of them toxic to humans?
MR. GALLAGHER: Objection. Form.
BY MR. SLATER:
Q. In your opinion?
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. Well, let me stop there.

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Let me ask the question differently.
Your evaluations of the toxicity of the listed pesticides, did you ever conclude that any of those pesticides were toxic to humans?
A. I don't remember the specifics of each of these. This is a general statement of my experience that I had over the years. Each -- and some of these were just ones when I worked with the State of Florida, as for the Bureau of Pesticides when I was regulating these pesticides. Some of it was part of my consulting career.
Some of these pesticides, certainly at high enough doses could cause toxicity in humans, obviously -- I'll quote Paracelsus -- if you have a high enough dose, could cause acute effects in humans.
So for each one of these specifically, I cannot recall the exposure circumstances that would be associated with each of these.

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And I don't remember -- my conclusions may have or may not have been or which may or may not have been involved in a specific request or if they were even in a litigation-type circumstance.
Q. Have you ever concluded that any of the pesticides listed here in this entry are toxic to humans at the exposure levels that would occur in normal use of those products in which they are contained?
MR. GALLAGHER: Object to form.
MR. INSOGNA: Object to form.
THE WITNESS: Repeat that again.
BY MR. SLATER:
Q. Sure. With regard to the whole list of pesticides here in this entry on your CV, have you ever concluded that any of those pesticides when used as intended are toxic to humans?

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MR. INSOGNA: Same objection.
MR. GALLAGHER: Objection to form.
THE WITNESS: No. Considering what they're used -- as they are intended to be used with proper equipment and according to labeled directions, I have not -- I have not concluded that they would cause harm to humans.
BY MR. SLATER:
Q. And that clues DDT?
A. Well, DDT is -- like I said, it's significant at sufficient doses it might. But DDT is still used, for example, in other countries in -- as a treatment for malaria in tents. So it's actually still used.
Q. Did you say it's still used in other countries?
A. Correct.
Q. But it's not used in the

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United States anymore?
A. I don't believe it is.
Q. Why's that?
A. I don't remember the reason that it's not used anymore at this time.
Q. Has there ever been a time in your career where you haven't been doing some work on behalf of a pesticide manufacturer?
I'm talking about after you left the State of Florida. So in your private toxicology practice, have you continuously been doing some work for pesticide manufacturers at all times?
MR. GALLAGHER: Objection to form.
THE WITNESS: No. No. It's sporadic work. My pesticide work is sporadic.
BY MR. SLATER:
Q. On Page 7 there's a heading, "Pharmaceutical Agents and Medical Devices."
Do you see that?

A. Yes.
Q. The first heading says, "Safety assessment of excipients used in pharmaceutical products. Evaluated the pharmacokinetic and animal toxicity data related to excipient compounds."
What matter was that?
A. That's confidential.
Q. What is an excipient compound?
A. Those are compounds that might -- may or may not occur in a pharmaceutical product. I was asked to evaluate the different excipients, the toxicity of those, or potential toxicity.
Q. Okay. About five or six down it says, "Assessment of side effects of a popular over-the-counter medication." And you were trying to determine whether Stevens-Johnson syndrome was causally associated with the product. What product was that?
A. That's confidential.
Q. It's acetaminophen, right?

A. We -- correct, yes. Yeah. The client is confidential.
Q. Yeah, I'm not asking who the client is.
A. Okay. Yeah, it was --
Q. Let me guess, you concluded that acetaminophen was not causally associated with Stevens-Johnson syndrome?
MR. GALLAGHER: Objection to form.
And I caution you the same caution to the extent that the substance of your opinions is confidential.
THE WITNESS: Right. I was not the expert in this case. I was just assisting.
BY MR. SLATER:
Q. Did you reach any conclusion in your mind as you were assisting?
MR. GALLAGHER: Objection to form.
THE WITNESS: Well, in this case in particular, the individual had already developed their condition prior to any use. So in this particular instance, there was no causation.
BY MR. SLATER:
Q. That was your opinion?
A. That was the opinion that was reached by the expert.
Q. When you say the expert, you mean the expert that you were assisting?
A. Correct.
Q. And that was a litigated matter, I suppose, right?
A. Yes.
Q. Go to Page 8, please. There's a heading that says "Regulatory Compliance."
A. Yes.
Q. The first entry says, "Evaluation of respiratory regulatory limit for caprolactam"?
MR. SLATER: I'll just spell it for Michelle.
C-A-P-R-O-L-A-C-T-A-M.

BY MR. SLATER:
Q. Do you see that entry?
A. Yes.
Q. And it says that you prepared rebuttal comments to OEHHA in California in response to proposed RELs," reference exposure limit -- levels.
What was this matter? What were you doing here?
A. For the client we were, or I was assisting in preparing rebuttal comments. I believe they were trying to -- I don't know if they were introducing a new regulatory limit or changing a limit. But we were just providing some commentary, because OEI usually allows people to respond to their -- any kind of new regulatory value or altered regulatory value. We were just preparing comments for that. Or I was assisting.
Q. Was your client a seller of caprolactam?
A. That would be confidential.

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Q. Were the rebuttal comments intended to convince this California body not to impose certain reference exposure levels?
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. Was that the intent of those comments?
MR. GALLAGHER: Objection to form.
THE WITNESS: The purpose of the comments were just to respond to the data they analyzed. We may have provided additional data to make it a more complete dataset. I don't recall the exact specifics. I'd have to go back and look at the comments, if I can find them.
BY MR. SLATER:
Q. What is caprolactam?
A. It's a chemical that's used in the -- as an additive to protectants,

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like repellants sometimes. It's an industrial chemical. It's not very common.
Q. In this regulatory compliance section, do they all relate to -- well, I'll withdraw that actually.
Is it fair to say whoever retained you on this caprolactam matter, intended to use your rebuttal comments to help convince that California body not to impose reference exposure levels that would have impacted their ability to sell caprolactam?
MR. INSOGNA: Object to form.
MR. GALLAGHER: Objection to form.
THE WITNESS: That's confidential.
BY MR. SLATER:
Q. Okay. If it's so confidential, why is it on your CV?
MR. GALLAGHER: Objection to form.

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THE WITNESS: The work is not confidential, what I did. It's just some of the details, or the client would be confidential.
BY MR. SLATER:
Q. I'm just asking for the purpose of the rebuttal comments. You're telling me that's confidential?
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. Let me just ask you, isn't it common sense that the manufacturer wanted the reference exposure levels not to be lowered to the point where it would affect their ability to sell the product? I mean, isn't that what these comments were about?
MR. GALLAGHER: Objection to form. Argumentative and asked and answered.
THE WITNESS: In some cases, they just want the body of evidence to be complete.

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BY MR. SLATER:
Q. Complete so that they wouldn't have their business impacted, right?
MR. GALLAGHER: Again, objection to form. Argumentative and asked and answered.
BY MR. SLATER:
Q. Do you recall? Can you tell me?
A. No, the same answer. As scientists, we want the body of evidence to be the most complete it is so we have a total comprehension and we have the full body to work with. We don't want portions of evidence or decisions to be made on just part of the evidence.
Q. So you thought that you were being hired just to make the evidence complete and that the client that hired you didn't have a purpose in submitting the information? Is that what you're telling us?
A. They didn't have --

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MR. GALLAGHER: Objection to form.
THE WITNESS: Sorry, they didn't have what?
BY MR. SLATER:
Q. A purpose in hiring you. They didn't have a motivation to influence the final decision by this body? They just were trying to be helpful?
MR. GALLAGHER: Objection to form.
THE WITNESS: I don't know what their purpose was. They offer -- we, and many other organizations, they are working towards transparency and involvement of individual scientists to be part of the process.
And that's what -- that's what we do, we work together and we try to get the best science out there.

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BY MR. SLATER:
Q. Going down to the bottom of the page, second-to-last entry, "Evaluation of vinyl chloride carcinogenicity. Conducted an assessment of the animal and epidemiologic evidence to determine whether a causal association exists between vinyl chloride and liver or brain cancer among individuals exposed to vinyl chloride in the environment."
Who retained you for that one?
A. I do not recall.
Q. What was the outcome of your evaluation in that matter?
A. Again, that would have been assisting someone else, another expert or a expert.
Q. Who?
A. So I would have just provided information, summaries of studies, and then let them reach their own conclusion.
Q. Who were you assisting?

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A. I cannot be completely sure at this time. I can look and see. This is an older evaluation.
Q. In your opinion, is vinyl chloride carcinogenic to humans?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes. It is -- it causes angiosarcoma in humans at high doses.
BY MR. SLATER:
Q. Are those high doses that would be encountered by humans in normal everyday life?
MR. GALLAGHER: Objection to form.
THE WITNESS: You'd have to give me the doses, and I'd have to do my analysis.
BY MR. SLATER:
Q. I'll ask the question differently.
You said at high doses it can be carcinogenic to humans. So my

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question is, when you use the word "high doses," are those the doses that you would expect people to be exposed to in day-to-day life?
A. No.
MR. GALLAGHER: Objection to form.
THE WITNESS: No, those are doses that existed in industry typically back in the '50s, I guess early days -- in the past, when the exposures were much higher in the industry.
These are not, you know, everyday environmental exposures that exist today.
BY MR. SLATER:
Q. With regard to all these matters -- actually, let me -- let's go to the next page, Page 9.
At the top of the page it says, "Toxicity assessment and toxicity profile generation for a former electronics site in Seminole county,

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Florida. Reviewed the toxicity of multiple chemicals for multiple diseases, generated toxicity profiles for benzene, freon, lead, methylene chloride, rosin, 1,1-dichloroethylene, 1,1,1-trichloroethylene, trichloroethylene, toluene, 1,4-dioxane and vinyl chloride. Provided thorough research regarding confounders for over 30 cancer and noncancer conditions?"

Who was the client in that matter?

A. That would be confidential.

Q. Was it a litigated matter?

A. I believe it was in litigation. We were just consulting. We weren't experts, or I wasn't an expert.

Q. Did you conclude that these chemicals had caused any harm to anybody? Or was that not your role?

A. That was not --

MR. GALLAGHER: Objection to form.

THE WITNESS: That was not

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our role. We were just tasked to say what the chemicals were and just basic, like, mini tox profiles and just provide the chemicals and the data, the animal, epi data.

BY MR. SLATER:

Q. Well, actually, it says you provided thorough research regarding confounders for over 30 cancer and noncancer conditions. What's a confounder?

A. That would be like if it was -- if there was -- I don't remember the specific cancers in this case. But if it was a breast cancer, we would say, well, if someone has BRCA or if they're obese, that would have been the type of confounder that we would have said.

Or if it was diabetes for noncancer, you know, we would have said are they obese or family history of diabetes.

So those would have been the

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confounders that we would identify.

Q. How do you define a confounder?

A. It's a risk factor for a condition or a disease.

Q. So when you were providing these confounders to this confidential client, you were providing them with analysis of other risk factors and alternative causes for the conditions complained of as opposed to this list of chemicals here. You were trying to help them defend the matter by pointing to other potential causes, right?

MR. GALLAGHER: Objection to form.

MR. INSOGNA: Objection to form.

THE WITNESS: I'm not sure what they did with the information. That's what we did, we provided confounders, and we provided the toxicity information.

BY MR. SLATER:

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Q. Well, you provided the confounders. But you did understand that that was the reason that they wanted these confounders is so they could point to alternative causes, correct?

MR. INSOGNA: Objection to form.

MR. GALLAGHER: Objection to form.

MR. SLATER: Can we have one person defend the deposition, please?

BY MR. SLATER:

Q. Can you answer the question?

A. Can you repeat it, please?

Q. You understood that the reason that you were retained was so that whoever retained you could point to alternative causes for the conditions that were being claimed in that matter, right? You understood that's why they wanted the confounders?

MR. GALLAGHER: Objection to form.

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THE WITNESS: I don't -- that's not my understanding. And confounders can be used when you're looking at a study. It can be used for other information. So I don't recall what they wanted that information for specifically.
BY MR. SLATER:
Q. It would seem to me, and you correct me if I'm wrong, that you would want potential customers or clients to see this and know that you're available to help them defend toxic exposure cases, this would be -- this would be something that would interest somebody who has to defend a toxic exposure case, that you will look for confounders to explain away potential toxic injuries, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: No.
BY MR. SLATER:
Q. Isn't that what you do? You represent industry for the most part, the

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vast majority of your work, industry entities who are defending themselves against claims that they produced some substance that's causing harm or could cause harm to humans. Isn't that what you do?
MR. GALLAGHER: Objection to form.
THE WITNESS: No.
BY MR. SLATER:
Q. No? Isn't that what you're doing here in this case?
MR. GALLAGHER: Objection to form.
THE WITNESS: No.
BY MR. SLATER:
Q. Do you know why you were hired in this case? Do you think you were hired to give helpful information, or were you hired to try to advance a litigation position on behalf of manufacturers who sold valsartan with NDMA and NDEA?
MR. GALLAGHER: Objection to

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form.
THE WITNESS: I was hired to evaluate the reported complaints or theoretical complaints that might appear in the future, to evaluate the doses, and to see what the theoretical excess cancer risk might be.
Most of my work is not litigation. It's a very small part of what I do.
BY MR. SLATER:
Q. Whether it's litigation or consulting, the vast majority of the work that you do is for manufacturers, sellers, or other entities that create exposures to potentially toxic substances, right? That's who --
MR. GALLAGHER: Objection to form.
THE WITNESS: That's not correct.
BY MR. SLATER:
Q. That's not the vast majority

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of the work that you do?
A. No.
Q. Well, we just went through a bunch of matters. I understand that you've told me virtually every one that I asked about it was confidential and you couldn't tell me the details. But in every single matter listed where there was a private client, it was the entity that was either selling a product that could potentially cause a toxic exposure or created a situation that potentially created a toxic exposure to humans, right? Every single one --
MR. GALLAGHER: Objection.
BY MR. SLATER:
Q. -- where you've done work for a public entity, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct. I do work -- sometimes it's a consumer product. It's a -- supplies food and they have something in their

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product that they're concerned about. And we evaluate it and say, yes, you have a concern, no, you have a concern.

So sometimes it's a consumer product. It may be a corporation, but it's done the same thing, or a pharmaceutical company, or it's -- or we do a lot of work for regulatory agencies also, I'd say 40 percent of my work over the last year has been for a regulatory agency.

I'm not going to say who it is, but probably only 20 percent of my work is litigation.

BY MR. SLATER:

Q. You're not going to tell me who the regulatory agency is?

A. That's confidential. It's not my client.

Q. Okay. Looking now there's a heading on Page 9. It says "Miscellaneous Projects." The first one

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says, "Evaluation of a possible cancer cluster. Study potential cancer clusters and whether these were relating to environmental exposures to dioxin."

Who was your client in that matter?

A. Again, that's confidential. It's an ongoing case. I don't feel comfortable talking about that.

Q. Are you retained by the entity that released the dioxin into the environment?

MR. GALLAGHER: Object. I caution you to the extent answering the question would force you to disclose --

BY MR. SLATER:

Q. Well, we know it's not --

MR. GALLAGHER: -- anything that's confidential.

BY MR. SLATER:

Q. We know -- let me ask it differently.

We know you're not retained

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by the plaintiffs who claimed they were harmed by the dioxin, because you already told us that you're not doing work for plaintiffs. So you're working on behalf of the entity that is being sued for releasing dioxin into the environment, correct?

MR. GALLAGHER: Objection to form. Again, to the --

THE WITNESS: This is confidential. I can't talk about this case.

BY MR. SLATER:

Q. You can't tell me which side -- well, rephrase.

You're not representing the plaintiff -- you're not -- rephrase.

You are not working on behalf of the plaintiff there, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: I am --

MR. GALLAGHER: Asked and answered. Go ahead.

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THE WITNESS: We're working for -- we are working for defendant. But you can't assume that they released anything.

You're -- it's --

BY MR. SLATER:

Q. The alleged release of dioxin into the environment. Is that what you're saying?

A. Correct.

MR. GALLAGHER: Objection to form.

THE WITNESS: Correct.

BY MR. SLATER:

Q. The last entry here says, "Lead toxicity presentations. Summarized the regulatory standards for lead and the toxicity of lead based on target organs and presented information to companies at their request."

Are you saying that over the years you've provided consulting work to companies who wanted information about the toxicity of lead?

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A. There was two presentations on this. And this is a very long time ago. I would say probably over 20 years ago. Companies that had maybe some elevated lead in their workers and they just wanted some information on toxicity and, you know, what levels were of concern and which were not of concern.

I did another presentation for kind of another -- it was like a general meeting or -- some kind of manufacturers, just kind of let them know what was of concern and not of concern.

Q. Did you tell them, "Don't worry, lead is not toxic to humans. You have nothing to worry about"?

A. No.

Q. Is lead toxic to humans?

A. It can --

MR. GALLAGHER: Objection to form.

THE WITNESS: It can be at certain concentrations.

BY MR. SLATER:

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Q. Are you aware of any circumstances that have ever occurred in the United States of America where lead exposure at sufficient concentrations occurred so that people developed diseases as a result? Has that ever happened in the history of the United States, to your knowledge?

A. Yes. Yes. I mean, there's children who ingest too much soil or too much paint with high levels of lead from the '40s or '50s can get elevated blood lead levels and have to undergo treatment. So, yes, it has occurred.

Q. How about drinking water, are you aware of any circumstance where levels of lead in drinking water was toxic to humans?

A. There has been instances where lead from old plumbing in homes has caused increased levels of lead in certain drinking water. I would have to have the concentrations and do that to tell if they were sufficient to cause

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blood lead elevations, versus other sources.

Q. Looking now at the heading "Publications," is that a list of your publications?

A. Yes. And as I said, there may have been a couple more that I've added since April.

Q. At the bottom of Page 9, there's one from 2016, "The role of systematic review in the practice of toxicology and risk assessment: In appreciation for the primary tool in evidence-based practices." Do you see that -- "approaches."

Do you see that?

A. Yes.

Q. Did you perform a systematic review in this matter? And the reason that I'm asking --

A. I was not --

Q. Let me just -- because I read your report, and I didn't see any reference to you performing a systematic

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review. I'm assuming the answer is no, but I want to confirm that.

A. That's correct.

Q. To your knowledge, did anybody in this matter perform a systematic review of any expert?

MR. GALLAGHER: Objection to form.

THE WITNESS: I would -- I would defer to other experts and how they would characterize their process or their methods or their review.

BY MR. SLATER:

Q. Did you read all the expert reports in this case from all the defense experts and all the plaintiff experts? Is that your understanding?

A. Yes, I did.

Q. Did any of them indicate in their reports that they performed a systematic review?

A. I can't recall right now if they used those specific words, no.

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Q. Did you see in any of the reports -- well, rephrase.
In reading the reports, did you determine that any of the experts for either side did perform a systematic review, whether they called it that or not? Did you see anybody perform a systematic review?
MR. GALLAGHER: Object to form.
THE WITNESS: I mean, in reviewing, for example, Dr. Fryzek's expert report as far as epi evidence, it appeared that he used methods that you would use in a systematic review.
BY MR. SLATER:
Q. But you're not sure if he did a full-blown systematic review or not?
MR. GALLAGHER: Objection to form.
THE WITNESS: It appeared that he completed a systematic

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review, and I know he has experience in that area.
BY MR. SLATER:
Q. What is a systematic review?
A. It's where you ask a question -- it's where you ask a question, it's a very, very specific question of what you're looking for. And you provide -- you conduct a targeted literature search.
And then you do the literature search. You identify the papers that are specific to your question that you're asking. And you review those -- those papers.
And usually you have a set of criteria against which you evaluate those papers, whether or not they -- depending on the type of paper. Sometimes you can rank and rate them based on the type of paper, like if it's cohort versus a case report.
So different people have a little bit different definition of

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systematic review or what they may or may not include, depending on the issue at hand and the type of evidence you're looking at.
Q. Can you go to Page 10, please.
A. Okay.
Q. There's a heading that says "Abstracts and Presentations."
A. Yes.
Q. Let me ask you, let me come back to one thing. I want to make sure --
A. Okay.
Q. In your list of publications, do any of those publications address at all the toxicity or potential risks associated with nitrosamines, NDMA or NDEA? I don't see it. I just want to make sure I'm not missing it.
A. No.
Q. Looking now at the heading "Abstracts and Presentations."

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A. Okay.
Q. Do any of those address the potential toxicity or risks associated with nitrosamines, NDMA, or NDEA?
A. No.
Q. At the top of page 11, one of your abstracts is titled "Mesothelioma Diagnosis: Should Genetic Screening Be Used to Evaluate Primary Site and Plausibility of Asbestos Causation."
Do you see that?
A. Yes.
Q. What were you communicating in that abstract?
A. Basically that the thought now is that for some mesothelioma, individuals, there's a component of genetics that come into play, especially some of the cases of younger age people who have like a family history of mesothelioma.
So it was just sort of an introduction to that. It is a little bit older paper.

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I think this was eventually published as a full paper, but I was not an author on that.
Q. There's a section headed "Book Chapters." Do any of those book chapters relate to nitrosamines, specifically the toxicity or risks associated with nitrosamines and NDMA or NDEA in particular?
A. No.
Q. Do any of the textbooks in which those chapters were found address the potential risks of nitrosamines, NDMA, NDEA? Is that addressed in any of those books?
A. I am not -- I do not know for the books themselves.
Q. The next heading is "Seminars and Continuing Education."
Do any of those relate to potential risks of nitrosamines NDMA or NDEA?
A. No.
Q. Let's go now if we could to

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Exhibit B to the report, which I guess we'll mark as Exhibit 5.
(Document Marked for identification as Exhibit Britt-5.)
THE WITNESS: So that would be Exhibit 3?
MR. GALLAGHER: It's Exhibit 5.
BY MR. SLATER:
Q. Testimony experience of January K. Britt, Ph.D., 2016 to 2021.
A. Exhibit 4?
MR. GALLAGHER: Exhibit B to your report. Exhibit 5, if you refresh.
THE WITNESS: Okay.
BY MR. SLATER:
Q. Is this a complete list of all testimony that you've provided from 2016 to the present?
A. Yes.
Q. During that time period, do you know how many reports you have

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written where you were not either deposed or didn't testify?
A. I would say approximately 20, 15 to 20.
Q. Did any of these litigated matters listed on this Exhibit B, which is Exhibit 5, relate at all to nitrosamines, the risks thereof, including NDMA or NDEA?
A. No.
Q. Let's go to Exhibit C now.
MR. SLATER: Mark that as Exhibit 6. This is exhibit C to the report of Dr. Britt.
(Document Marked for identification as Exhibit Britt-6.)
BY MR. SLATER:
Q. This document just indicates what your fee schedule is. Is that accurate for what you've been charging in this matter?
A. Yes.
MR. SLATER: Chris, do you

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have -- let's mark as Exhibit 7, Chris, and put up the invoice or the collection of invoices, I should say.
(Document Marked for identification as Exhibit Britt-7.)
MR. GEDDIS: Do you want them all combined? I'm just going to have to put them together.
MR. SLATER: You gave them to me stapled together.
MR. GEDDIS: That is true.
MR. SLATER: I don't think I want to do them one at a time. I think that will take a while.
Is that something that we can do?
MR. GEDDIS: No.
MR. SLATER: I'm sorry. No what? You can't put them together?
MR. GEDDIS: I'm putting them together. But I need to do

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it.
MR. SLATER: All right. We'll come back to them then.
You know what, Chris, just put up the first one. 4/15/19. Then during a break you can scan them or have someone scan them in and send them to you, and then we can just identify it. But let's go to April 15, 2019. Mark that as Exhibit 7.
MR. GEDDIS: They are all in the exhibit now.
MR. SLATER: I'm sorry, Chris. What did you say?
MR. GEDDIS: They are all Exhibit 7 now.
MR. SLATER: Oh, they're all combined?
MR. GEDDIS: Yes.
MR. SLATER: But they're not in any sort of an order, I guess, right, because the one up on the screen is August 11, 2020?

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Look, just leave it. Just -- if you can get to the first one, that would be great. If they're in order, that would be awesome. But I don't want to take a lot more time on it.
Chris, can you put it up, please? I don't care which one is first. I just want to move on.
Chris, please just put the combined invoices on the screen.
Perfect. Okay.
BY MR. SLATER:
Q. On the screen we have Exhibit 7, which is the invoices that we were provided by defense counsel. And the first one is April 15, 2019.
First question, is that the first invoice in this matter?
MR. GALLAGHER: I don't think what's on the screen is the exhibit. What's on the screen is a 21-page document. And the exhibit that I have is 16 pages.

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MR. SLATER: I don't know what -- I don't understand.
MR. GALLAGHER: I'm saying what you have on the screen is not the document.
MR. SLATER: April 15, 2019 invoice. Is that the invoice that's on the screen?
MR. GALLAGHER: Okay. There's a new Exhibit 7 uploaded.
THE WITNESS: Oh, is there?
MR. GALLAGHER: It's called Exhibit 7 complete.
THE WITNESS: There it is.
MR. GALLAGHER: Thank you.
BY MR. SLATER:
Q. Okay. Start over.
Exhibit 7 is the invoices we were provided by defense counsel.
Are those all the invoices that you have provided to defense counsel since the start of your retention in this matter?
Are these your invoices,

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Doctor?
A. Yeah, I'm trying to make sure they are all through -- 8/21. Yeah, this should be all of them.
Q. The first one is April 15, 2019. Is that when you were first retained in this matter?
A. Yes, that's the approximate date.
Q. This is on a -- I'm going to call it a letterhead of IMS Expert Services. What is that company?
A. That's a company that I guess is best described as they help individuals locate experts for whatever needs they might have for consulting.
Q. Were you retained through IMS Expert Services in this matter?
A. Yes, and they -- they are the ones that contacted me initially.
Q. So --
A. I was retained through them.
Q. So if I understand correctly, the Duane Morris lawyers went

to IMS Expert Services, would have said something to the effect of we're looking for a toxicologist for this matter, and IMS identified you and put you in touch with Duane Morris, and that's how you got involved in this matter? Am I correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: I'm not aware of the background of how I was contacted or who would have talked to who.

BY MR. SLATER:

Q. If you were hired directly and they didn't go through IMS, IMS wouldn't be involved, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: Can you repeat that?

BY MR. SLATER:

Q. Sure. If the Duane Morris lawyers had come to your company directly, not through IMS, but had just

come to you directly to hire you, IMS wouldn't be involved, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: That's correct.

BY MR. SLATER:

Q. So we can agree that Duane Morris went to IMS, described the type of expertise or described this case or whatever they told them, and IMS then connected Duane Morris with you correct?

MR. GALLAGHER: Objection to form. Objection to form.

THE WITNESS: Correct.

BY MR. SLATER:

Q. Who is paying IMS Expert Services for your involvement in this matter?

MR. GALLAGHER: Objection to form.

THE WITNESS: I am assuming Duane Morris, the people I'm representing or working for are

paying IMS.

BY MR. SLATER:

Q. Do you know what IMS is being paid in connection with your work in this litigation?

A. I do not.

MR. SLATER: We're requesting that information.

THE WITNESS: Yes.

MR. GALLAGHER: We'll take it under advisement.

MR. SLATER: I'm saying that -- I'm saying that more for the record.

MR. GALLAGHER: Yep.

BY MR. SLATER:

Q. Is IMS doing anything in connection with this case other than what they've done so far, which is connect you with Duane Morris and issue your invoices? Have they had any other --

MR. GALLAGHER: Objection to form.

THE WITNESS: Have they had

any other -- what was the last part? I'm sorry.

BY MR. SLATER:

Q. Involvement.

A. No.

Q. For example, are they helping do research or are they helping prepare exhibits, or are they doing anything in connection with your involvement in this case, to your knowledge?

A. No.

Q. Is your firm -- well, rephrase.

Does your company pay IMS when they identify you as an expert and you're then retained in a matter?

A. Could you repeat that?

Q. Let me ask you this. Does your company pay IMS for the fact that they're -- that they have you on their list, first of all?

A. No. No. No.

Q. When you get retained

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through IMS's services, does your company pay IMS?
A. No. No.
Q. Has your company paid anything to IMS in connection with the valsartan litigation?
A. No.
Q. So to your knowledge, any payments to IMS would have been made by Duane Morris or the defendants together, to your knowledge?
A. Correct.
Q. I've added up all the amounts. Actually, I'm not going to make that up.
Somebody added up all the amounts on these invoices between April 15, 2019, and the last invoice we have, October 23 -- rephrase. Let me withdraw that.
We added up the amounts of each of the invoices, with invoice dates April 15, 2019, through the last date we see of September 8th, 2021, and came up

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with a number of 274,606.20. Does that sound about right for what you invoiced through September 8, 2021?
A. I have not added them up. So I would have to add them up.
Q. I'm also advised that there's work done where -- rephrase.
I'm also advised that these invoices include charges for them -- for IMS finding articles, which is not included in that amount.
So I'm putting that aside in that amount.
Does your answer remain the same, you haven't added them up?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. Why is IMS obtaining literature? Why are they doing that?
MR. GALLAGHER: Objection to form.
THE WITNESS: I wasn't aware

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that they were. I usually -- our library gets those articles either through RightFind or our librarian -- or my librarian gets it through her sources.
BY MR. SLATER:
Q. So any charges that you see here for obtaining literature, you would expect that that was work that your firm performed and charged for, correct?
A. Correct. I don't interact with IMS on any -- anything related to my report.
Q. Why does IMS issue the invoices? Why doesn't your company issue the invoices?
MR. GALLAGHER: Objection to form.
THE WITNESS: That's just the arrangement that was agreed upon.
BY MR. SLATER:
Q. Is there also an arrangement that if you perform future work for this

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client, that IMS will also be paid for -- in connection with that work in the future as well, since they've introduced you to this client?
A. No.
Q. So you can get introduced one time, do the assignment, and then go work for that client going forward without telling IMS or paying them?
MR. GALLAGHER: Objection to form.
THE WITNESS: I do not know. I do not know the answer. I don't know what -- that's never occurred, so I don't know the answer to that.
BY MR. SLATER:
Q. Do you have -- rephrase.
Can you tell me how much time has been spent on this matter since the September 8, 2021 invoice?
A. Probably been another 40 hours.
Q. And what has that been --

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rephrase.
And what have you done in those approximate 40 hours?
A. Just, you know, get ready for this deposition.
Q. So you've spent 40 hours preparing for the deposition approximately?
A. Well, reviewing new materials or new reports that were sent last minute.
Q. I have not been provided any supplemental expert reports indicating any change to your opinions. So am I correct that the opinions in your report have remained the same, regardless of anything that you've seen since you issued your original report?
A. Yes.
MR. SLATER: Let me go off the record for a second.
THE VIDEOGRAPHER: The time right now is 12:07 p.m. We are off the record.

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(Short break.)
THE VIDEOGRAPHER: The time right now is 12:25 p.m. We're back on the record.
MR. SLATER: Okay. We're back on, right?
BY MR. SLATER:
Q. When did you --
THE VIDEOGRAPHER: We're back on.
MR. SLATER: Okay.
BY MR. SLATER:
Q. When did you first become aware of the contamination of valsartan with NDMA and NDEA?
MR. GALLAGHER: Objection to form.
THE WITNESS: I do not recall the specific date.
BY MR. SLATER:
Q. Did you know about it before you were contacted to work in this litigation?
MR. GALLAGHER: Objection to

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form.
THE WITNESS: I believe I -- I had seen it in the news or CNN.com.
BY MR. SLATER:
Q. Had you done any reading or research on the topic before you were retained?
A. No.
Q. So you may have seen a news report about it, but you didn't go any deeper, that was the sum total of your knowledge about this situation before you were contacted?
A. Yes.
MR. SLATER: I think the next exhibit is eight.
Chris, could you put up the article titled "How Industry Scientists Stalled Action on Carcinogen."
Exhibit 8, please.
(Document Marked for identification as Exhibit

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Britt-8.)
BY MR. SLATER:
Q. Doctor, have you ever seen this article?
A. No, I don't recall seeing this article.
Q. This starts off right under the title and says, "For the past 60 years, water polluted with chromium has plagued Hinkley, California, the dessert town made famous by the film Erin Brockovich. Although residents there won their lawsuit against the polluter, Pacific Gas & Electric Company, there's still a debate over whether the compound causes cancer in drinking water. The Environmental Protection Agency says yes, but industry scientists disagree."
Do you see that?
A. Yes.
Q. First of all, has your firm ever been retained by Pacific Gas & Electric Company?
A. Repeat the question.

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Q. Has your firm ever been retained by Pacific Gas & Electric Company?
A. I do not know.
Q. Let's go to Page 2 out of 11 of this article.
A. Okay.
Q. The second paragraph says, "Some of the most powerful voices in the debate are companies with a stake in the outcome.
They've hired scientists to convince regulators that the chemical compound is safe. The lawsuit that Brockovich championed was merely the beginning of an intriguing tale about corporate manipulation of science?"
Do you see that?
A. Okay. Okay. I see that.
Q. As a general matter, would you agree with me that to the extent that corporate manipulation of science has occurred in any context involving potentially toxic substances, that would

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be a bad thing?
MR. GALLAGHER: Objection to form.
THE WITNESS: Repeat the question.
BY MR. SLATER:
Q. Sure. Would you agree with me as a general matter that any corporate manipulation of science in the context of a potential toxic exposure, would be a bad thing?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you define "corporate manipulation"?
BY MR. SLATER:
Q. I would define corporate manipulation of science as corporations hiring scientists to advance scientific positions that are not valid for the pecuniary gain of those corporations.
A. Yeah, I would agree that you would not want to hire a science -- scientist that was going to advance --

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advance your -- the science towards -- just for your gain. Yes, I agree. That would not be a good thing.
Q. As a toxicologist, it would never be ethical for you to engage in the corporate manipulation of science or to assist in the corporate manipulation of science, correct?
A. As you define manipulation, that's correct.
Q. Would it also be unethical to deliberately advance a one-sided position on a question of whether a toxic exposure is potentially harmful to humans?
MR. GALLAGHER: Objection to form.
THE WITNESS: Repeat that question.
BY MR. SLATER:
Q. Sure. Would it be unethical for you as a toxicologist to advance a position that is one-sided, deliberately one-sided, to only focus on some of the

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evidence in order to advance a corporate position that a toxic exposure was not dangerous to humans?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you define "deliberately one-sided"?
BY MR. SLATER:
Q. Knowing that there's other scientific information of significance that's directly relevant to the points that you're making, and you deliberately don't reference the other side of the coin.
MR. GALLAGHER: Objection to form.
THE WITNESS: I guess I -- yeah, I agree. You should always look at all the evidence and then reach a conclusion based on overall totality and strength of the evidence. That's what I was saying earlier about the caprolactam or anything, you know,

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where the government wants your input. If you got input or someone's got input, whoever wants to respond or input, has the ability to do it. That's what transparency is about, so it's not one-sided.

BY MR. SLATER:

Q. Let's go back to this article now, the third paragraph on Page 2 out of 11. I'm going to read through this by way of context to lead up to part of the article a little further down.

It says, "In 2008, the national toxicology program, part of the National Institutes of Health, published ground breaking research detailing how mice and rats that drank heavy doses of a toxic form of chromium called chromium-6 developed cancerous tumors. The findings prompted the Environmental Protection Agency to act."

Do you see that?

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A. Yes, I see that.

Q. And do you understand what the National Institutes of Health is?

A. The National -- the National Toxicology Program or -- yes, yes, I know who that is. Yeah.

Q. What is the NIH?

A. It's part of the government that conducts research and oversees health. National Toxicology Program is part of that. It's sort of a research arm. They conduct some kind of generic chronic cancer bioassays in animals.

Q. Going down to the next paragraph, this states, "EPA scientists evaluated hundreds of studies and concluded that chromium-6 likely causes cancer in people who drink it. The agency in 2011 was on the verge of making its scientists' findings official, a first step toward forming more stringent clean water rules.

"But last year, it bowed to pressure and announced it was going to wait for new studies being paid for by the chemical industry."

Do you see that?

A. Yes.

Q. By the way, when did you start working at ToxStrategies?

A. I believe it was 2012.

Q. Reading further down.

"To lead those studies, the American Chemistry Council, the industry's main trade group and lobbyists, hired ToxStrategies Inc., a Texas-based firm with scientists experienced in poking holes in research that links chromium to cancer.

The company describes its business this way on its website: 'We often interact and collaborate with regulatory, academic, and industrial professionals to ensure that the most appropriate science is incorporated into each assessment?'"

Do you see that?

A. Yes.

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Q. And you're aware, are you not, that ToxStrategies was retained by the American Chemistry Council to lead the studies to try to establish that chromium-6 was not cancerous to humans, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: I -- that was before I was hired. And I do not know -- I know that -- you know, we've -- some people at our company have done chromium work. But I do not know the details of that work or who the clients are.

BY MR. SLATER:

Q. Were you aware that your company was hired as described in this article?

MR. GALLAGHER: Objection to form.

THE WITNESS: I do not have any knowledge of this, no.

BY MR. SLATER:

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Q. You're learning about the involvement of ToxStrategies, Inc., in this matter that I'm reading to you about here, with the chromium-6, you're learning about it for the first time right now as we're reading through this article?

MR. GALLAGHER: Objection to form.

THE WITNESS: Like I said, I know that there are some individuals at our company that do chromium-6 or have -- you know, are interested in chromium-6, have looked at chromium -- chromium-6, published papers on it.

But I don't follow chromium to any great degree. I know a little bit about it, but I am not sure of the inner workings of anything described in here.

MR. SLATER: I want to go to another document. And of course, I'm going to skip one that we

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discussed. I want to go to the heading Natural Resources Defense Council.

(Document Marked for identification as Exhibit Britt-9.)

BY MR. SLATER:

Q. In front of you, Doctor, we have --

MR. GALLAGHER: Is it in front of her yet? Is this an exhibit?

MR. SLATER: I'm sorry. What are you asking, Patrick? Is this an --

THE WITNESS: It just popped up.

MR. SLATER: It's Exhibit 9.

THE WITNESS: We have a little bit of a delay here.

MR. GALLAGHER: Got it.

THE WITNESS: I have it.

BY MR. SLATER:

Q. On the screen we have

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Exhibit 9, which is an August 16, 2018, set of comments from the Natural Resources Defense Council on the Environmental Protection Agency's TSCA systematic review.

Do you see that?

A. Yes.

Q. Are you familiar with this issue?

A. I have not -- I have not seen this document.

Q. This says -- rephrase.

To give a little more detail right on the front page, it says, "Comments on the application of the TSCA systematic review to the exposure and use assessment and human health and environmental hazard summary for five PBT chemicals." And then there's an EPA number.

Do you know what PBT chemicals are?

A. Persistent, biopersistence. I can't remember what the T stands for.

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Usually chemicals that persist in nature.

Q. Let's go now to Page 7, please.

A. Okay.

Q. Looking at Page 7, the first full paragraph says, "The TSCA systematic review fails to account for the significance of rare adverse outcomes in studies with limitations or a lower statistical significance."

Do you see that? Do you see that sentence that I just read?

A. Yes. I see it. Yes, I see it.

Q. Do you agree with me that in evaluating a question of causation or potential causation, it's important to account for the significance of rare adverse outcomes in studies with limitations or a lower statistical significance?

A. If I'm reading this right, they're saying that the EPA assessment does not properly account for adverse

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outcomes, study limitations or if they've got a low significance. I believe if there is something statistically significant, it needs to be considered. But I don't know if they're -- I'm not sure how they are defining lower statistical significance.

Certainly if the study has got significant limitations, it renders it unreliable. It doesn't need to be included in a systemic -- systematic review. So I'm not sure of the context that NRDC was writing this sentence. I haven't reviewed this whole, entire document, so.

Q. My question was more a general question. I'll try to ask it a little bit more differently.

A. Okay.

Q. In order to have a valid methodology, is it important to account for the significance of rare adverse outcomes that may result from a toxic exposure?

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MR. GALLAGHER: Objection to form.

THE WITNESS: It's important to consider if something is a rare adverse outcome, there's -- you should look at the study type, if it was the correct study to look at rare adverse outcomes. There're certain study types that are better at looking at.

There's ways of looking at background control data if you're looking at animal studies.

So I think it's important that you do it. But you've got to look at how you do it.

So like, again, I'm not sure what the context of what they were seeing here.

BY MR. SLATER:

Q. Well, I'll read a little further --

A. So if you could --

Q. Yeah, sure. I'm going to

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read a little further now in the context of this document, and then that will lead us up as context to the next paragraph.

This document states, "We are particularly concerned that the EPA Toxics Office plans to use its systematic review to discard the scientific evidence linking the rare outcome of congenital heart defects with trichloroethylene (TCE).

"The heart effects are rare but can be disabling or even deadly. Based on a transparent systematic review of the scientific evidence, EPA scientists determined that there were some uses of TCE in consumer and industrial products that were so dangerous they should be discontinued. In particular, EPA scientists had raised concerns with low dose exposures during pregnancy that could lead to permanent heart malformations in the developing fetus."

Do you see what I just read?

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A. Yes.

Q. Now, continuing, they state, "However, recently the ToxStrategies consulting firm published a list of biases with the TCE heart studies that it contends should make the study unusable for regulatory purposes. Its analysis and conclusion follow the criteria laid out in the TSCA systematic review. Significantly, ToxStrategies received funding from Entek" -- E-N-T-E-K -- "International, whose Oregon-based battery parts operations have been repeatedly fined for violations related to its TCE pollution, including allegedly poisoning its workers."

And it points to an article in The Oregonian, May 6, 2017.

"Thus ToxStrategies itself also had a financial bias, something that the TSCA systematic review does not include in the risk of bias analysis as discussed further below?"

Do you see that?

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A. I see that.
Q. First of all, are you familiar with this situation, which this document was dated August 16, 2018?
MR. GALLAGHER: Objection to form.
THE WITNESS: No. I have not seen this particular -- no, I've not seen this document.
BY MR. SLATER:
Q. Are you familiar with this TSCA systematic review issue, or are you telling me --
A. No.
Q. -- you're hearing about this one far the first time also?
MR. GALLAGHER: Objection to form.
THE WITNESS: I have not seen the five PBT TSCA systematic review. I was unaware of this specific issue. I know that there is in general controversy about the effects of TCE in the heart

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based on animal studies and how they are extrapolated to humans.
I suspect that they are talking about the Johnson study here.
This is something that's been considered for many, many years. They've tried to recreate the Johnson study in animals, and they've had a hard time.
As far as it relates to this specifically, I do not know. And I know that's something that I've looked at this before in other matters before the years, it's been -- it's been an issue in the scientific committee so -- community.
But as far as it relates to this specific NRDC document, I've not seen it, and I'm not aware of the specific Oregon battery -- Oregon-based battery parts operation. I'm not aware of this.

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MR. SLATER: You can take that down. Let's go to the next article. That is Exhibit 10. FERC study.
THE WITNESS: Okay.
(Document Marked for identification as Exhibit Britt-10.)
BY MR. SLATER:
Q. Looking now at Exhibit 10, this is an article titled "FERC Study Finds No Risk From Protective Coating of Mountain Valley Pipeline" dated October 8, 2020.
And this caption talks about a chalky substance being found and a concern about it degrading into nearby water and soil and that the federal energy regulatory commission found no basis for the fears about this coating.
Do you see that?
A. Yes. I see -- I see that.
MR. SLATER: Let's go to Page 2 out of 5.

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BY MR. SLATER:
Q. Right in the middle of the page there's a paragraph that says -- hang on one second.
Looking at the top of the page, the second paragraph says, "In a report released Thursday, the Federal Energy Regulatory Commission addressed concerns that had been raised about the Mountain Valley pipeline."
And if we go down three more paragraphs, this states, "The report cites the conclusion of ToxStrategies, a consulting firm hired by Atlantic Coast that there should be no impact on human health or the environment from the chalky residue that forms on the pipes after prolonged exposure to sunlight." And Atlantic Coast is the pipeline company.
Do you see what I've just read?
A. I see that.
Q. Are you familiar with this matter?

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MR. GALLAGHER: Objection to form.
THE WITNESS: I have not heard of this matter. It sounds like the Energy Regulatory Commission had -- you know, there was concerns raised, and ToxStrategies basically said there was no -- no impact on health or environment.
So I'm not familiar with this matter. I don't know what the chemical was or anything about this.
BY MR. SLATER:
Q. We've just gone through a few articles talking about various matters your company has been involved in. And it's fair to say that this is representative of the type of work your company does. It works on behalf of industry to try to reduce or eliminate regulation that could impact those clients' businesses, right?

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MR. GALLAGHER: Objection to form.
THE WITNESS: I would not phrase it that way. I say we get calls or requests from -- sometimes it's industry. Sometimes it's regulatory agencies to -- where there's a concern.
And we evaluate the literature, we look at the exposure, and we look at the doses, and we come to a conclusion based on whatever concern or alleged concern there may or may not be.
We do all kinds of work. We do work for, like I said -- I don't want to give clients' names out.
But we do for regulatory agencies all over the world, in the United States, we do work for, you know, companies of course that provide consumer products, foods,

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trying to keep, you know, consumers safe as far as industry. So we do a wide variety of work.
MR. SLATER: We can take that down, Chris.
BY MR. SLATER:
Q. Let's go back to your report.
MR. SLATER: Chris, we don't need to put it up on the screen. I think as long as the doctor has a copy. This way we can see a little easier, I think.
BY MR. SLATER:
Q. If you need it put on the screen, let me know.
A. Okay.
Q. But this way I don't have it blocking my view.
A. Okay.
Q. I'm looking at your report. I'm on Page 10, your executive summary.
A. Okay.
Q. What is the purpose of the

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executive summary? Is that just what it says, a general summary of what you looked at and a summary of your opinion?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes, it's just an overall summary of the report, just condensed into a few paragraphs.
BY MR. SLATER:
Q. You start off and state, "In this matter, the plaintiffs, through their experts, are arguing novel hypotheses that rely on many uncertainties, assumptions and unknowns."
So I want to stop there. The hypothesis that -- rephrase.
Using your term, the hypothesis that NDMA is a human carcinogen is not a novel hypothesis, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you repeat

your question?
BY MR. SLATER:
Q. Sure.
You referred to novel hypothesis. In fact, the hypothesis that NDMA is a human carcinogen is not novel, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: It's not -- it's not a known human carcinogen.
There's several regulatory agencies, scientific societies, that have come to that conclusion after evaluating the data.
So in that aspect, it would be novel or something that needs to be considered or evaluated.
That's why we're here.
BY MR. SLATER:
Q. The hypothesis that NDMA is a probable human carcinogen is not novel, correct?
MR. GALLAGHER: Objection to

form.
THE WITNESS: It is a -- you know, regulatory agencies such as IARC and EPA have classified it as a, you know, probable human carcinogen based on animal data, not based on -- it's not a known human carcinogen. There's not sufficient data to conclude that it's a human carcinogen.
BY MR. SLATER:
Q. Coming back to my question. The hypothesis that NDMA is a probable human carcinogen is not novel, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: That's correct, with the caveats that I have.
BY MR. SLATER:
Q. So when you said that the plaintiffs, through their experts, are arguing novel hypotheses, that's not entirely accurate, because the hypothesis

that NDMA is a probable human carcinogen is not a novel hypothesis, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: I guess that assumes that the plaintiffs are not going to say it's a human carcinogen.
BY MR. SLATER:
Q. Have you read any of the expert depositions of any of the plaintiffs' experts?
A. I have not reviewed those.
Q. If the position taken by the plaintiffs is that NDMA is a probable human carcinogen, you would agree that's not a novel position to take, right?
A. That's correct. It's still not to the level of a known human carcinogen.
Q. You would agree with me that the description of NDMA as a probable human carcinogen is accurate, correct?
MR. GALLAGHER: Objection to

form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. You refer to -- I'm sorry.
You refer to reliance on many uncertainties, assumptions, and unknowns.
Do you see that?
A. Yes.
Q. You would agree with me that the plaintiffs' experts are not solely relying on what you would term uncertainties, assumptions, and unknowns, right?
A. Repeat the question.
Q. Sure.
You referred to the plaintiffs' experts relying on many uncertainties, assumptions, and unknowns.
You say "many."
You're certainly not saying that all of their opinions are based solely on uncertainties, assumptions, and unknowns, right?

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MR. GALLAGHER: Objection to form.
THE WITNESS: Correct.
BY MR. SLATER:
Q. You would agree with me that at least, to some extent, the plaintiffs' experts are relying on what you would agree is solid science, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: What is your definition of "solid science"?
BY MR. SLATER:
Q. Science that encompasses a valid methodology and reasonable conclusions.
MR. GALLAGHER: Objection to form.
THE WITNESS: Well, if the plaintiffs' experts are going to say it's a known human carcinogen, I don't think that it's reached that level of evidence.
And there's many regulatory

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agencies that of course have that same opinion.
BY MR. SLATER:
Q. My question is not as to their conclusions. My question has to do with what they relied on in forming their conclusions. And as I just defined solid science, you would agree that at last to some extent, the plaintiffs' expert are relying on solid science, right?
MR. GALLAGHER: Objection to form.
MR. INSOGNA: Objection to form.
THE WITNESS: Some of their studies I would say do not contribute to any -- or not -- would not normally be included in the overall -- or not meet the criteria of what would be included in a good evaluation, as can be seen in other -- some of the other experts, like some of the epi studies.

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You probably need to defer to Dr. Fryzek to ask him questions about the certain studies.
But some of the information I would say is not based necessarily on solid science or wouldn't meet overall the level of what would be included, say, like, when IARC included those, because I'm sure they evaluated some of the same studies that IARC did, but they reached different conclusions, so.
BY MR. SLATER:
Q. So the flip side of what you said would be accurate, that some of what the plaintiffs' experts relied on, you would agree is solid science, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Some of the statements they may have made are -- would be accurate, correct.
BY MR. SLATER:

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Q. In terms of whether or not a person's cancer was caused or not caused by NDMA or NDEA, that's a medical conclusion that you're not drawing, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Repeat the question.
BY MR. SLATER:
Q. Sure. You told me before you're not going to be providing medical opinions. Medical causation as to whether a person's disease was actually caused or contributed to by, in this case, NDMA or NDEA, that's not something you're opining on. That's a medical opinion, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah, so for a specific plaintiff, like for a specific -- I mean, as far -- you mean diagnosis, like, for a

physician, I wouldn't be, like, making an actual diagnosis of a plaintiff or an individual.

But as far as specific causation, you know, assuming that there was general causation for this, which there is not, you know, one can go about and do a dose exposure calculation to see what the risk is. But for this case, you couldn't -- there would be no need to do a specific exposure analysis, because there's no general cause of it.

But no, I would not be diagnosing a plaintiff or doing a differential diagnosis, because that would be for a physician to do.

BY MR. SLATER:

Q. You say in this first paragraph of your executive summary that, "Accepting these premises," meaning the premises of the plaintiffs' experts,

"would mean that there are literally hundreds if not thousands of other potential chemical causes of the alleged diseases that now cannot be excluded objectively using a proper specific causation analysis."

Do you see that?

A. Yes.

Q. So you're lumping together NDMA and NDEA with hundreds if not thousands of other potential chemical causes? Is that what you're saying?

MR. GALLAGHER: Objection to form.

BY MR. SLATER:

Q. And you're saying they're all fully uncertain?

A. I'm not saying -- I'm not saying they're uncertain. I'm just saying that if you're going to assume that NDMA or NDEA is a human carcinogen and you're going to presume they're capable of causing, at these low doses, someone's cancer, you need to also

consider all the other hundreds or thousands of chemicals, and I detailed this later in the report, that we're all exposed to on a daily basis, in the air, diet, drugs we take, the radiation from medical exams, all those different things that we get.

And I noted too in my report that Panigrahy has one paper where he talks about different mechanisms of cancer and he states there's basically 1,400 carcinogens.

So even Dr. Panigrahy recognizes there is a multitude of potential chemicals out there that, you know, we just get exposed to potentially in our daily human lives. So...

Q. Would you agree with me that NDMA -- well, rephrase.

Would you agree with me that the scientific consensus is that NDMA is among the world's most extensively tested agents for carcinogenicity?

MR. GALLAGHER: Objection to

form.

THE WITNESS: I would agree that it's been tested in a large number of species. And there is a lot of research. I don't know if it's among the most. I haven't done that analysis to see where it ranks in studies.

BY MR. SLATER:

Q. The scientific consensus is that NDMA has consistently demonstrated carcinogenicity in multiple different animal species, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: That's correct. In animal species, yes.

BY MR. SLATER:

Q. That is a fact of significance that any expert looking at this question of general causation would need to take into account, right?

MR. GALLAGHER: Objection to form.

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THE WITNESS: Yeah, I mean, that was considered, I think, by most of the experts. And it's a probable animal carcinogen. But it's still -- the human evidence doesn't raise it to the level of a human carcinogen.

Like I said, other agencies have looked at that, looked at all the totality of the evidence and the mechanistic evidence, and they also agree that it's just not to the level of a known human carcinogen.

BY MR. SLATER:

Q. With regard to animals, NDMA and NDEA are not probable carcinogens. They are animal carcinogens, correct?

A. That's correct.

Q. That's a significant fact that would have to be taken into account by any expert applying a valid methodology in this case, right?

A. That's correct.

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Q. Do you say anywhere in your report, that NDMA and NDEA are animal carcinogens? I'm just curious. I didn't see that. I'm just curious if you said that anywhere in your report.

A. Yeah, on Page 32. I say, "While NDMA and NDEA have found to be carcinogenic in several animal species."

Q. That's where you were recognizing the fact that they are known animal carcinogens, right?

A. Correct.

Q. Because of the evidence as to the carcinogenicity of NDMA and NDEA in animals, you would not want to lump that together with hundreds or thousands of other chemical substances that have not achieved that level of certainty, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: Can you repeat the question?

BY MR. SLATER:

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Q. Sure. Because NDMA and NDEA are accepted as animal carcinogens, as we've discussed a moment ago, you would not want to lump them together in your analysis with hundreds or thousands of other chemicals that have not achieved such a level of certainty, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: That's correct. Like I said, even like Dr. Panigrahy stated, he stated there's over 1,400 carcinogenic chemicals.

So even he's admitted there's numerous carcinogens in the environment that we are potentially exposed to.

MR. GALLAGHER: When you get to a point, can we take a break?

MR. SLATER: We're talking lunch now?

MR. GALLAGHER: For lunch, yeah.

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MR. SLATER: Sure.

MR. GALLAGHER: If you have, like, five more minutes of questions or we can break now.

MR. SLATER: Yeah, break now. I've got a bowl of berries in front of me.

Let's go off the record.

THE VIDEOGRAPHER: The time is 1:08 p.m. We are off the record.

- - -

(Whereupon, a luncheon recess was taken.)

- - -

THE VIDEOGRAPHER: The time right now is 1:57 p.m. We're back on the record.

- - -

BY MR. SLATER:

Q. I think I neglected to ask you at the very outset. Your title is managing scientist. What does that mean?

A. Well, I guess at

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ToxStrategies, we have, I guess, like a different -- types or levels of individuals, like, when we have a Scientist 1, 2, or 3, depending on your level of experience or education.

So managing scientist is sort of, I guess, just where I'm at in my career and my experience. So there's levels above me obviously and levels below me. So but that's just where I'm at.

I'm a toxicologist still. But just where I'm at is a managing scientist. Means that there will be people that, you know, help me do work or, you know, things like that, there are more senior managing scientists, I think. It's just kind of a hierarchy in the company.

Q. Does it indicate any particular responsibilities or is it just the hierarchy of seniority or whatever that may be?

A. It's just a hierarchy of

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seniority, just based on, like, you know, what affiliations you have, kind of like where you're at in your career, publications, degrees, things like that.

Q. Okay. The next thing that I'd like to ask you about is evidence-based toxicology.

First question is, what is evidence-based toxicology as you use that term?

A. Evidence-based toxicology is basically -- has its basis in evidence-based medicine, which has been around for a fairly long time. But it's still used by physicians in forming opinions on treatment methods and treatment regimens for patients.

It was derived out of the need -- since physicians are so busy and they can't evaluate all the literature that comes out on any treatment or a new medication or new procedure for a patient or for a specific disease, evidence-based medicine was -- came about based on that.

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So, basically what it is, you do a -- like I said, initially -- earlier, you start with a systematic review, and you -- so you can look at the evidence-based methods, it's called. They are guidelines that kind of -- that's the basis of evidence-based toxicology.

You basically set out a question, what your specific question that you're asking, like does chemical X at a certain level cause disease Y?

And then you formulate your literature search. You do that. Then you evaluate your literature, and you can -- if you want you can rank and rate it based on the types of literature.

If you've got human literature, for example, you would put your -- if there's any randomized control trials, you put those first, and then cohort and case-controls. So it just goes down. There's a hierarchy that, you know, most individuals follow. And it's

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simple to find.

Then after that you can evaluate it further based on the doses, like, an individual gets or you can use some kind of further criteria, causation criteria. There is temporality, coherence of evidence, to kind of further refine your conclusions.

So it's basically meant to be a transparent methodology that's systematic that if it's out there, anyone that follows that should be able to come to the same conclusions that you do.

And we published a paper on this in 2015, I believe. It was, like, a ten-year retrospective of evidence-based toxicology.

And since that time a lot of agencies, regulatory agencies, you know, IPSA, EPA, even IARC is sort of trying to take that method and approach that they use to be transparent, you know, invite people in to see the process, make sure it's transparent. They're incorporating

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systematic reviews into their process to make sure they get all the evidence.

So it's basically -- longwinded review -- what it is.

Q. I wanted to make sure I have an understanding. And I think what we can probably do right now is put up this.

MR. SLATER: We're up to, I want to say 11. But if I'm wrong, correct me if I'm wrong. The ten-year retrospective article.

(Document Marked for identification as Exhibit Britt-11.)

MR. SLATER: I'm not sure I'm right about the exhibit number.

MR. GEDDIS: I think you are correct.

BY MR. SLATER:

Q. We've marked as Exhibit 10 (sic), the article titled "Evidence-Based Causation in Toxicology: A Ten-Year Retrospective." And you're one of the

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authors of that, correct?

A. Correct.

Q. This starts off indicating, "We introduced evidence-based toxicology (EBT) in 2005 to address the disparities that exist between the various weight of evidence (WOE) methods typically applied in the regulatory hazard decisionmaking field and urged toxicologists to adopt the evidence-based guidelines long utilized in medicine, i.e., evidence-based medicine (EBM)."

So I want to stop there and just establish a few things. One, this proposed methodology you said was introduced in 2005. And that would have been another article authored by Robert James and a few other people in 2005, correct?

A. Correct.

Q. I'm going to go through some terminology first.

You referred to weight of evidence methods. And that's -- weight

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of evidence is a methodology to evaluate a question of causation, right?

A. Yeah. It's one of the terms that people use. It's kind of a -- it can be a kind of a catchall kind of term.

But, yeah, that's -- that's one of the terms that people use when they're evaluating any causation.

Q. When you refer to evidence-based medicine -- and I think you talked about it before, that doctors in the medical field have applied that to treatment decisions, correct?

A. Right. Right.

Q. Evidence-based medicine is not a causation concept. It's a concept that is supposed to support treatment decisions, correct?

A. Well, so evaluate what the best -- you know, using whatever criteria, if it's the Hill criteria, whatever criteria it is that they use to decide which is the best treatment. Like if it's for a stroke or for a new

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heart -- you know, new medicine for a heart disease or whatever, they'll use -- it's the same methodology considering, you know, all the different -- it's basically the same. It's not -- you asked a question, you get your literature, and then you evaluate the literature.

So the systematic review part is the same part.

Q. Just to come back to my question. Evidence-based medicine is a concept intended to be utilized in the context of making treatment decisions, correct?

A. That's correct. That's correct.

Q. It's not a causation methodology when it's used in the medical field, right?

A. It's used to -- it's used to make decisions on the best -- or if a treatment is the best -- or if it's an accurate, or if there's adequate

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information to use that treatment or not. So it's a yes or no decision that's made on a specific treatment.

I'm not sure if causation is the best word.

Q. Well, I just want to make sure we're clear with our terminology here. Evidence-based toxicology, as posed in the 2005 and 2015 articles, is a causation concept, a methodology to evaluate questions of causation, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: Correct.

BY MR. SLATER:

Q. Evidence-based medicine is a methodology used by medical doctors to make treatment decisions, not to evaluate causation questions, correct?

A. That's --

MR. GALLAGHER: Objection to form.

THE WITNESS: That's true. The basic -- you know, it's to

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make decisions on various treatment. But the methodology is the same. Or it's based on similar methodologies.

BY MR. SLATER:

Q. The weight of -- rephrase.

The weight of evidence methods that you contrast to EBT in your article, are accepted methodologies to evaluate causation questions, right?

MR. GALLAGHER: Objection to form.

MR. SLATER: Let me ask it differently.

BY MR. SLATER:

Q. The weight of evidence methodology to evaluate a causation question is an accepted methodology in the scientific community to evaluate questions of causation, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: Repeat the question.

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BY MR. SLATER:

Q. Sure.

The weight of evidence approach is an accepted, recognized methodology to evaluate questions of causation, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: I would say, as I said before, weight of evidence is sort of a general kind of catchall term, like when we described in our paper, there's -- we looked at 52 -- you know, there's other papers, like this Reference 17, 52 different weight of evidence frameworks.

So do you have a specific one that you were talking about or just the weight of -- what exact -- can you expand further?

BY MR. SLATER:

Q. My understanding of weight of evidence -- well, why don't we do

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this.

Why don't you tell me what your understanding is as to what the weight of evidence approach is, as a generic matter, to evaluating causation questions. What does that mean? Because you contrast weight of evidence with evidence-based toxicology in your article.

So you've told me what EBT is. Now I'm asking you to describe to me what weight of evidence means.

A. Well, weight of evidence, like I said, it's a general -- it's a general phrase, and it can mean different things to different individuals. And that was sort of the problem in some of these evaluations, that one person may just say, oh, you know, I just looked at all the animal studies or some of the animal studies, or, you know, I looked at a few of the mechanism studies or I just looked at four papers. So -- and then I just made a decision. Or someone may say

I just looked at a review article, you know, or whatever they said.

So this was set out to have, like, a set methodology that people could follow. And like I said, other regulatory agencies, IRIS, IARC, they're all starting to use systematic review, evidence-based toxicology because they see that's a good transparent way that people can follow and they can reach the same decisions if they follow the same set methodology.

Whereas, weight of evidence can be different types of methods, and they vary depending on whose -- whose weight of evidence methods you look at.

Q. Are you able to tell me what weight of evidence means as you understand it with any more specificity than what you just told me?

A. No.

Q. Did you just say that regulatory agencies -- and I think you said all of them -- are starting to now

utilize evidence-based toxicology? If you said that, that would have been a misstatement, because all regulatory agencies have not adopted EBT as a methodology, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: No, they have not. I said some of them are starting to approach EBT-like methods or evidence-based or systematic review into their methods to become more transparent.

For example, the one document that you showed earlier from Environmental Defense Fund, that was, I think, them responding to a TSCA systematic review.

So EPA just started using systematic review not to long ago.

So that was kind of an advancement -- you know, an advancement in the way EPA

analyzes chemicals is to use a systematic review.

Similar, IARC is using systematic review now, and they're starting to come up with a methodology that's repeatable, that whenever they have their meetings they all follow the same method. So that's what that means.

BY MR. SLATER:

Q. You're not saying that the term "systematic review" is inherent to evidence-based toxicology, because that term has been in the literature long before 2005, right?

A. Yeah, it's --

MR. GALLAGHER: Objection to form.

THE WITNESS: It's part of evidence-based toxicology.

BY MR. SLATER:

Q. So evidence-based toxicology coopted and incorporated a systematic

review as part of the EBT methodology; is that correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: I like to say coopted. It incorporates the method of systematic review as part of the process of EBT.

BY MR. SLATER:

Q. Let me try to ask it clean. And I appreciate you clarifying because I realized when I asked the question, the two things -- they might have sounded pejorative, the coopt part. So I didn't want it to sound that way.

If I understand correctly, this concept of EBT incorporated the already existing systematic review methodology as part of this proposed EBT methodology. Do I understand that correctly?

A. Yes. That's correct.

Q. So when EBT is carried out as intended, part of that process is a

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systematic review.
Do I understand that correctly?
A. Yes.
Q. And I think what you said is some regulatory bodies are starting to incorporate systematic reviews into their evaluations of questions.
Did I understand that correctly?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah. Some of them are starting to incorporate systematic reviews into their process of looking, whenever they assess a chemical or an exposure or -- into -- into their assessment process, like EPA for example.
BY MR. SLATER:
Q. You are not saying that, for example, the EPA or another regulatory agency has explicitly come out and said,

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"We adopt EBT as a methodology we're utilizing." You're saying they're utilizing certain aspects of what is part of EBT as part of their evaluations of certain questions.
Do I understand that correctly?
MR. GALLAGHER: Objection to form.
THE WITNESS: I'd have to look and see if they specifically spelled it out, EBT.
I know that in, for example, like in 2006 the National Academy of Science criticized -- I believe it was the EPA, and said, you know, when you do your risk tox assessment, when you do your assessment, you need to follow the criteria -- causation methods, similar to those in Guzelian in 2005, which is the precursor article to this.
So there have been agencies

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that have said, "Look, you need to follow this type of EBT method."
Whether or not they called it out, EBT, there may be examples of that. I would have to check. I know that this method has been referred to.
BY MR. SLATER:
Q. The EBT method, if I understand correctly, has been proposed in 2005 by your colleagues. You then co-authored the ten-year retrospective in 2015. And if I understand correctly, this is a methodology that has been proposed and is being considered, but you would not say it's been accepted as a scientific methodology across, for example, toxicology, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: I'm not trying to say that every toxicologist uses evidence-based toxicology. But it has expanded into the field

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and is becoming more accepted.
There's -- SOT has evidence-based toxicology, you know, subforums. There's publications about it. So it's certainly becoming more prevalent in the field of toxicology.
Again, not every toxicologist practices, you know, causation. Some do research. Some do -- and it's -- and if you're in the field where you're assessing whether or not a chemical causes some kind of disease or in fact, you know, like, when the EPA does their assessments for IRIS, they're getting closer and closer to this type of assessment.
BY MR. SLATER:
Q. Is that in the context of what you told me earlier, that they're performing systematic reviews?
A. Yes. That's part -- that's

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part of it, yes.
Q. Is there another part of it?
A. Well, I'm not sure about their causation part. I'd have to go and look at their documents. I know they just updated their IRIS document about how they perform their assessments. I'm not sure if they've applied, like what kind of causation criteria they're putting in there. I'm not sure.
Q. I got it. So you're -- I appreciate the clarification. So you're telling me the EPA and these other regulatory agencies are starting to incorporate systematic review or aspects of what you described as EBT as part of their evaluations of questions that they're addressing, you're not saying this is something that's now been accepted for their evaluation of causation questions, though. You're differentiating, correct?
MR. GALLAGHER: Objection to form.

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THE WITNESS: I would have to look at the causation part and see who all, you know, has accepted that as part of their actual assessment process.
This has been -- in the last two or three years it's kind of been moving along quite rapidly. So I would need to see who has finally accepted certain things and who hasn't.
BY MR. SLATER:
Q. Would you agree with me that EBT is considered to be favorable as a methodology to an entity that is being sued or a claim being brought against or a regulatory action being brought against regarding a potential toxic exposure?
MR. GALLAGHER: Objection to form.
THE WITNESS: I mean, it's a transparent, repeatable method that should be able to be used -- can be used by anybody. And

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that's why regulatory agencies are starting to use this type of method, systematic review, because you are required to lay out your methods.
A lot of journals now will actually say, you know -- like there are certain guidelines that you have to follow, like the ARRIVE guidelines if you're doing experimental research.
If you're doing a meta-analysis, or even if you're doing a systematic review there's actually guidelines to follow if you're going to publish a systematic review. So you have to follow those guidelines.
So for example, if I am peer reviewing a journal article for somebody, they're like, "Make sure they follow these guidelines." So you have to go -- did they, you know, follow this? Did they do

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that? Did they mention -- you know, so there's -- it's starting to get more incorporated and, you know, there's systematic review journals. So I went on a tangent there.
BY MR. SLATER:
Q. With regard to this EBT concept, things that you told me about is once you do the literature search, you evaluate, you rank, and rate the literature, right?
A. Correct.
Q. You said something to the effect of the human literature as the top of the hierarchy. Did I understand that correctly?
A. Yes.
MR. GALLAGHER: Objection to form.
THE WITNESS: Yes. If you have human literature, that's the most relevant literature for looking at causation. If you

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don't have any human, you would go to animal.

So there's a hierarchy. Even within the human literature, there's a hierarchy of study design that is stronger and goes to a weaker -- like randomized control trial is considered the gold standard. But if you don't have that, then cohort is the next best, and then you kind of go down from there.

BY MR. SLATER:

Q. In order to properly undertake an EBT method -- rephrase.

In order to apply an EBT methodology as intended, if I understand correctly, you have to place the human literature at the top of the hierarchy if it exists, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: If there is -- if there's -- you know, you would

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lab -- you would evaluate the human literature. And if it's -- if it's, you know, high quality literature, you know, a priori, you set out your quality for ranking and rating, your -- I think there's even a table here that talks about that.

Yeah, so you would rank and rate your studies. A priori means before you start doing it, to eliminate bias.

So you would say when I look at these studies, I want to make sure they have a control group, and if the control group is matched, and they looked for confounders, and they, you know, looked at the medical records, and they had, you know, realtime exposure data, not just self-reported data.

So you set out this list of criteria that you want to evaluate

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your studies on. And then you get the studies, and then you evaluate them against the criteria that you picked out a priori, again, beforehand.

You look at your studies, and then you make your decision based on the best quality studies, the highest ranking type of studies, cohort versus, like, a case report of one person. And then you can go from there.

BY MR. SLATER:

Q. In this matter in the valsartan context, there's obviously no RCT, right?

A. Correct.

Q. There's no randomized controlled trial where you had a group of people given valsartan with NDMA or NDEA impurities at the levels seen with the pills here, and then have a separate group that took valsartan that was confirmed not to be contaminated at all.

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That study has never been done to your knowledge, right?

A. That's correct.

Q. And you wouldn't expect such a study to be performed, correct?

A. No. I mean, we do have the epi study so that -- conducted so far on the individuals who have taken valsartan so far. And we have the data on those individuals. So we have those studies. And then --

Q. So in this case, in terms of the hierarchy of human data, which sits at the top according to EBT, there's no RCT, so you go to the next level, and that would be the cohort studies that you've talked about?

A. Correct. That's the next in the hierarchy or the pyramid, if you will.

Q. In terms of the cohort studies that are most significant, would those be the studies that looked at people that took valsartan?

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MR. GALLAGHER: Objection to form.
THE WITNESS: Repeat the question.
BY MR. SLATER:
Q. Sure. In terms of the human epidemiologic studies, would I be correct that the ones that you would say are most prominent would be the ones that evaluated people who were taking valsartan during the time period when the contaminated pills were on the market and comparing people who took the contaminated versus people that you assume took pills that were not contaminated?
That's the -- that's the epi studies that you would put at the top in terms of significance, right?
A. Yeah, if I'm understanding you right, so the -- if you look at number one, on the EBT, so you would, you know, collect and get all the relevant literature, but before you would ask your

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question, so you would say -- and it has to be specific, like did NDMA or NDEA in valsartan cause specific cancer, or is it a known human carcinogen or does it cause cancer.
So the valsartan-exposed studies would be, you know, the best studies to look at as far as whether or not there's any risk there. So that would be your kind of highest priority to look at.
Is that what you're asking.
Q. Right. I'm trying to identify in terms of your hierarchy in looking at whatever existed in terms of literature, the Pottegard, Gomm and Al Kindi studies would be the most significant because those are ones based on cohorts of people that were taking the contaminated valsartan, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct.
BY MR. SLATER:

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Q. One of the things I like to do is I like to try not to go down a road that I don't need to. And I think based on what you told me earlier, in terms of the study design, the strengths and weaknesses, the limitations, any problems or issues with those epi studies, you would defer to the epidemiologist that was retained by the defense. You would really defer to that person on those questions, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: That's correct. I mean, I can talk about basic high level study problems or study design. But yes, as far as the overall opinions, I will defer to other experts.
BY MR. SLATER:
Q. For example, to the extent there was an issue in the Pottegard study with uncertainty as to whether or not the people on both sides of the study

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actually fit the criteria and how that would impact a statistical analysis or the strength of the findings, that would be something that I would talk to the epidemiologist about, right?
A. Yes, correct.
Q. In terms of just the gross conclusions from those studies, my understanding is in Pottegard, there was an increased risk for colorectal and uterine cancer shown, but in both of those cancers, the findings did not reach statistical significance. Does that sound correct to you?
MR. GALLAGHER: Objection to form.
THE WITNESS: I'm going to pull -- if it's okay, can I pull up that study?
BY MR. SLATER:
Q. Sure.
A. Okay. Can you repeat your question?
Q. With regard to the Pottegard

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study, there was a finding of increased risk for colorectal cancer and uterine cancer, but neither finding reached statistical significance, correct?
A. That's correct.
Q. Even though those increased risks did not reach statistical significance, you would still want to take them into account in evaluating the question before you, right?
A. Yes, I would take them into consideration, but they would not have any significant influence over the overall conclusions as, you know, as they were or were not significant.
Q. When you just said not significance -- rephrase.
You mean they wouldn't have significance to the ultimate -- the ultimate conclusion -- let me ask it differently.
In forming your opinions, did you factor in that in a study of only 5,150 people, which I believe the study

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said in Pottegard, they showed increased risks for colorectal cancer and uterine cancer, albeit not reaching statistical significance. Was that something that you factored into your analysis?
MR. GALLAGHER: Objection to form.
THE WITNESS: I considered it as part of my analysis, but because these were not significant findings, it did not change my conclusion that NDMA or NDEA were human carcinogens.
BY MR. SLATER:
Q. And again, to follow up on what I was asking before. To the extent that the sample size of just over 5,000 people could have some impact on interpretation of the data, that's something that you would defer to the epidemiologist on that specific granular question, correct?
MR. GALLAGHER: Objection to form.

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THE WITNESS: Yes, I'll defer to other expert.
BY MR. SLATER:
Q. In terms of the ultimate conclusions in Gomm -- which was the German study with hundreds of thousands of people, correct?
A. Correct.
Q. In Gomm, there was no finding of an increased risk for what they determined, quote, any cancer, just across-the-board overall risk for cancer, but they did make a finding of a statistically significant increased risk for liver cancer, correct?
A. Can we pull that study up?
Q. You can. I don't have it with me. I'm --
A. Okay. Okay.
Q. I mean, we can get it. But you can certainly pull it up.
A. Okay.
Okay. Can you repeat the question, please?

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Q. I was afraid you'd ask that.
A. Sorry.
Q. No, that's okay. In the Gomm study, which was a study of hundreds of thousands of people in the German health insurance database, there was no finding of an increased risk for, quote-unquote, any cancer, but there was a finding for a statistically significant increased risk for liver cancer, correct?
A. Yes. The adjusted HR, or hazard ratio, was 1.16, and the confidence interval was 1.03 to 1.31. So yes, it was slightly significantly elevated.
Q. That's a finding --
A. But --
Q. I'm sorry. Go ahead.
A. I was going to say but when they looked at -- when they did additional analyses, there was no risk for exposure versus non-exposure among long-term users. And when they looked at dose-response, there was no dose-response

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relationship based on dose exposure categories, that's in Table 2.
So just to add that.
Q. All right. Just coming back to my question, with regard to liver cancer, the Gomm study made the finding of a statistically significant increased risk for liver cancer, correct?
A. Yes, it did.
Q. That is a significant finding in terms of your approach to this question, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Again, I considered -- I considered that finding as I would have, you know, all the findings. There was -- in the Pottegard study there was no liver cancers.
And then the -- there was another study I think I looked at in my report. And then the Yoon study didn't find -- let me look.

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BY MR. SLATER:
Q. I didn't ask about Yoon, did I?
A. Well, I was saying that -- yeah, so I considered that. But Gomm didn't -- I mean, Pottegard didn't find any liver cancers at all in their study.
Q. All right. Just coming back to my question.
The finding of a statistically significant increased risk for liver cancer is something that you certainly needed to take into account, right?
A. That's correct.
Q. And as you told me a moment ago, you gave very little, if any, significance to the uterine cancer and colorectal cancer increased risks in Pottegard because they were not statistically significant, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: That's

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correct.
BY MR. SLATER:
Q. So if you're going to apply the same methodology in terms of statistical significance because liver cancer did reach statistical significance in Gomm, that would be a significant finding, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: Technically it was a significant finding, but the effect of that finding was diminished by the other non-meaningful findings in Table 2 where there was no dose-response relationship and there was no relationship with exposure with long-term users.
BY MR. SLATER:
Q. I'm not asking you about how you can evaluate that beyond what I'm asking. I'm not getting into the other level, or any other levels on it.

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Just -- I'm really just trying to go step by step.
A. Okay.
Q. So let me just ask it again.
The finding of a statistically significant increased risk of liver cancer in Gomm was a fact of significance to you that you needed to take into account in forming your opinion in this case, right?
MR. GALLAGHER: Objection to form.
THE WITNESS: I took it in consideration, yes.
BY MR. SLATER:
Q. And in terms of why there may have been no finding of liver cancer in Pottegard while there was a finding of statistically significant increased risk for liver cancer in Gomm, in terms of how the sample size or other aspects of the epidemiological analysis may have impacted that, again, that's something that you would defer to the

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epidemiologist, right?
A. That's correct.
Q. I want to walk through your methodology a little more. So we talked about the fact that the human studies would be at the top of the methodology -- rephrase.
In terms of your EBT methodology, we talked about the fact that the human studies, and in particular those studying people who actually took the valsartan with the impurities would be at the top of the hierarchy, correct?
A. Correct.
Q. In terms of what you also looked at in addition to those studies, what else did you factor into that analysis? I want to go step by step.
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. So let's go to the next level. Is there other epidemiology not of people that took valsartan that you

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looked at, that you thought was of significance to you in your evaluation?
A. I'd like to -- I looked at studies that included -- I think it was Iwagami and Yoon.
Q. What was the first one you said?
A. Iwagami.
Q. Are these the ranitidine studies?
A. Pardon me?
Q. Are these the ranitidine studies?
A. Yes. Yes.
Q. In terms of -- let me ask you this. Did you look at the dietary studies?
MR. GALLAGHER: Objection to form.
THE WITNESS: No, I did not look at any of the dietary studies. I did not consider those in my analysis. I looked at them briefly when I was looking at some

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of the other expert reports. But it was my understanding that the other experts did the evaluation of the dietary studies.
BY MR. SLATER:
Q. So you didn't look at the dietary studies because it was your understanding that other experts were going to evaluate that for the defense?
A. Correct. In depth, yes.
Q. Did you look at animal studies as part of your evaluation?
MR. GALLAGHER: Objection to form.
THE WITNESS: I looked at the Peto studies. I would defer to other experts as far as the in depth evaluation of animal studies.
BY MR. SLATER:
Q. You just saved us a lot of time. So I'm going to thank you for that. I have a big stack over here that I don't have to go through with you now.

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So that's good.
I didn't see any discussion in your report regarding the mechanistic studies of human tissue and evaluating that in contrast to animal tissue and how mechanistically DNA adducts could be impacted and all of that.
I didn't see an analysis of that as part of your evaluation. Am I correct, that wasn't part of it?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah. That was -- yeah, that was not part of anything I was asked to do. There was other experts that I would defer to for those questions -- or those issues.
BY MR. SLATER:
Q. Obviously there's discussion of animal studies in your report, and for example, there's a very lengthy discussion generally about animal to human extrapolation in Appendix A. Is

that generally for background regarding how animal studies might fit into such an analysis, but is it limited to that background information?

MR. GALLAGHER: Objection to form.

THE WITNESS: Yeah, it's a general, you know, discussion of extrapolating from animals to humans and sort of some of the shortcomings that have been associated with that type of extrapolation.

BY MR. SLATER:

Q. One of the things that you said as part of the discussion of methodology is one could incorporate another methodology into your analysis under the EBT approach.

Did I understand that correctly, or did I get confused really bad?

A. I think it was --

MR. GALLAGHER: Objection to

form.

THE WITNESS: -- the weight of evidence. The weight of evidence is kind of an umbrella term for just different types of methodologies that individuals have used in the literature, over time, to evaluate whether or not a compound can cause a certain disease.

If you just look up in PubMed weight of evidence, you'll get a lot of different hits and different people will use different methods.

You know, one person may just look at rat studies or certain studies, or they may only look at a subset, or they may not do a literature search, you know.

It just varies among individuals. And so there's kind of a move to have a more systematic, you know, reproducible

process that everyone can follow and follow along with and see how it's done.

BY MR. SLATER:

Q. I know I asked an unartful question now. Let me ask it again and try to do it in a more comprehensible way.

A. Okay.

Q. As part of the EBT approach -- and if I misunderstood, you can tell me. I thought you said as part of that approach, other methodologies can be incorporated in, for example, like a Bradford Hill analysis could be done, I guess. Or is that something that's a separate methodology, and I misunderstood?

A. No, that's --

MR. GALLAGHER: Objection to form.

THE WITNESS: That's part of the last part of EBT, is, you know, once you have your

literature, and you do your assessment, then you can sort of do an assessment of all the literature, and you look at how, you know, there's coherence and dose-response and temporality. So it's sort of the last part of the evaluation.

BY MR. SLATER:

Q. Got it. And I went through your report, and I did not see a Bradford Hill analysis performed. That's not something that you did here, correct?

A. No. I was not -- that was not part of what I was asked to do.

Q. Going back to your article now, Your 2015 article on evidence-based causation in toxicology. Do you have that still handy?

A. Okay. Yes.

Q. Look at Page 1246, please. It's the second page of the article.

A. Okay.

Q. In the bottom left hand

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column towards the end, you state, "In a similar vein, while our original article stated, and we still accept as true, that human data are the most valid metrics to determine human causality, EBT does not call for eliminating the consideration of animal studies."

That's an accurate statement of this methodology, correct?

A. That's correct.

Q. You continue, "In fact, our publications have consistently argued that when human data are insufficient to answer human causation and human risk questions, the regulatory risk assessment process will derive conservative health-protective exposure guidelines in the interim." Correct?

A. That's correct.

Q. When you refer to the regulatory risk assessment process, would that be, for example, the FDA setting the acceptable intake levels for NDMA in pharmaceuticals? Is that an example of

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that?

MR. GALLAGHER: Objection to form.

THE WITNESS: That might be an example that you could say, you know, you could look at that. But I think that's -- it's -- you know, we have human -- we have some human evidence that's been looked at, and it has been raised to that the level of human carcinogenicity.

And I think there's enough evidence that, in the regulatory risk assessment process -- so regulatory agencies like FDA or EPA, will often derive, you know conservative, health-protective exposure guidelines, even when there is human evidence, just because that's sort of what, you know, is in the nature of what they're tasked to do.

BY MR. SLATER:

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Q. In terms of the regulatory focus, you referred to it being health protective. That's because the regulators like the FDA, they want to make sure that they don't allow an unacceptable risk to be put out into the public, right?

A. Right. Right. So they're protective, they're conservative, they're proactive, they're -- and then there's even some language -- like, for example, the EPA, they say that they're risks are protective, they're not predictive.

So they're not -- their risks are for broad populations. They're not meaning to predict that any type of illness is actually going to occur. They are just being protective.

And what's inherent in that is that they've got uncertainty factors that based on animal evidence, which is -- animals are for the most part more sensitive than humans. So they've got all this extra protectiveness in there.

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So and even --

Q. All I'm -- I didn't mean to interrupt.

A. No, no I'm done. I'm done.

Q. Yeah, all I was driving at is really just the small question of the regulatory agency, like, for example, the FDA, is tasked with being health protective and avoiding unacceptable risk to the public. That's their goal, right?

MR. GALLAGHER: Objection to form.

MR. INSOGNA: Objection to form.

BY MR. SLATER:

Q. If I understand what you're writing right here.

A. Yeah, that's their goal. That's not what I was asked to do. But that is -- that is their goal, to derive something that will protect the population. That's their task.

Q. And you got to my next question.

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You didn't form opinions as to the rightness or wrongness of the regulatory decisions as to whether or to what extent valsartan could be sold with certain levels of contamination. You weren't judging that.

You were looking at a different question, which is whether or not those levels in your opinion would be sufficient to cause cancer in humans. Do I understand that correctly?

A. That's correct.

MR. GALLAGHER: Objection to form.

THE WITNESS: That's correct.

BY MR. SLATER:

Q. Just to take it one step further, if I'm understanding correctly, you see it really as two completely different questions, one question is what is an acceptable or unacceptable risk in terms of protecting the public health from a regulatory perspective, is one set

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of questions.

A completely different set of questions is, would a certain level of a particular substance, in this case NDMA or NDEA, be sufficient, in your opinion, to cause cancer in humans as those pills would be taken for the time period that they were taken.

Am I right about that, that these really are two different questions that don't overlap?

MR. GALLAGHER: Objection to form.

THE WITNESS: Yeah, so the FDA is being protective. They derived a conservative value that someone could be exposed to for a lifetime, for those two compounds -- or well, other -- nitrosamines, NDMA and NDEA in particular for this case.

And what I was asked to do and what I did is I considered, you know, the low doses, the doses

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that plaintiffs -- potential plaintiffs were exposed to based on the duration they were exposed to.

So I did a more specific risk based on the theoretical risks that the FDA derived to get a more -- a more specific risk based on the particular exposure of the plaintiffs.

BY MR. SLATER:

Q. So for example, to the extent that a decision was made, for example, by one of the manufacturers, and that they stated this publicly that, "The exposure to the impurity n-nitrosodimethylamine (NDMA) that was detected in valsartan product line presents an unacceptable carcinogenic risk to the intended patient population," and therefore, that's why the recall occurred, you're not taking issue with that, and you're not evaluating whether it was the right or wrong decision to

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stop selling it.

You're looking at actual causation of actual cancer in humans. Do I understand that correctly?

MR. GALLAGHER: Objection to form.

THE WITNESS: That was an FDA statement, you said?

BY MR. SLATER:

Q. That's a statement I read, frankly, from a press release from ZHP when they announced their recall.

A. Okay. Could you read that --

MR. GALLAGHER: Objection to form.

THE WITNESS: Could you read that again?

BY MR. SLATER:

Q. Sure. "The exposure to the impurity n-nitrosodimethylamine (NDMA) that was detected in valsartan product line, presents an unacceptable carcinogenic risk to the intended patient

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population."
So that's a statement as to the decisionmaking to stop selling the drugs with this impurity. That's not what you're focusing on. You're focusing on, would this actually cause cancer in humans. Do I understand that?
MR. GALLAGHER: Objection to form.
THE WITNESS: I haven't seen that document. Do you have that document?
BY MR. SLATER:
Q. I do. I have it right here. I'm just trying to understand, to the extent that ZHP said it was an unacceptable carcinogenic risk to the intended patient population, and thus they stopped selling the pill, and as you know, that was the decision made by the FDA in announcing the recalls, that's not -- you're not quibbling with that, you're not focusing on that, because that's a regulatory decision about

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whether or not these drugs should be in the marketplace, based on regulatory standards.
You're looking at a different question, which is causation of cancer and whether or not people are getting cancer or will get cancer from the pills. Do I understand that correctly?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah, that's correct. I'm not going to make a regulatory assessment decision on -- on that.
BY MR. SLATER:
Q. And to the extent that these regulatory agencies and pharmacopoeias, et cetera, made the decision that, even at the trace levels found, the presence of NDMA and NDEA was considered unacceptable, so these pills should not be sold with those impurities, again that's not something that you are

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disputing, it's a completely different question from the one that you're answering, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah, I'm not -- I don't have an opinion on that.
MR. SLATER: Bear with me a second. I'm trying to clean up my desk --
THE WITNESS: No problem.
MR. SLATER: -- and the room. And I'm sure you'd feel really bad for me for the mess that's in here, or not. I know that Patrick feels bad.
BY MR. SLATER:
Q. Does EBT posit that only human studies can establish that a chemical causes harm to humans, or is capable of causing harms to humans?
A. I don't know if it makes that statement. I don't think we make

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that statement.
Q. Do you agree -- I'm going to ask you a general question now.
Do you agree that a toxicologist cannot guarantee that a certain dose of a chemical will never cause an injury to a particular person?
MR. GALLAGHER: Objection to form.
THE WITNESS: Can you repeat the question, please.
BY MR. SLATER:
Q. Sure. Do you agree that a toxicologist cannot guarantee that a certain dose of a chemical will never cause an injury to a particular person?
MR. GALLAGHER: Objection to form.
THE WITNESS: I don't know if we can absolutely 100 percent guarantee that something would never happen. But we -- based on the data that we have and our ability to look at exposure-dose

relationships within animal studies and human studies, we can predict with a pretty good likelihood what would happen.

Say, for example, like, with alcohol, we know like if someone drinks one drink, what's going to happen, two drinks what's going to happen. You can predict blood alcohol levels and the effects the blood alcohol.

So, you know, with chemicals, with enough data, we can have a pretty good idea of what's going to happen with certain doses and exposures.

But if a chemical doesn't have much data, it gets a little harder. So it's going to be chemical specific.

BY MR. SLATER:

Q. Sorry. I'm just trying to find -- I wrote down something. I was on a certain page, and I can't figure it

out. Bear with me for one second. Okay. Let me ask again because I think I understand your answer, but I want to make sure we're situated on this one narrow question.

Do you agree that a toxicologist cannot guarantee that a certain dose of a substance will never cause an individual -- or an injury to a particular -- let me rephrase.

Do you agree that a toxicologist cannot guarantee that a certain dose will never cause an injury to a particular person?

MR. GALLAGHER: Objection to form.

BY MR. SLATER:

Q. And I'm using the word guarantee deliberately.

MR. GALLAGHER: Objection to form.

THE WITNESS: Like I said before, we have good data on the compound. We have a fairly good

ability to predict what's going to happen dose-responsewise with a chemical, and if toxicity is going to occur within the dose range of the data for which we have exposure information and dose information.

MR. SLATER: Chris, do you have available the transcript from the Scott versus Dyno Nobel case from March 23, 2018?

THE WITNESS: I don't think so.

MR. SLATER: Oh, I'm not asking you. I'm asking Chris.

THE WITNESS: Oh, go ahead.

MR. SLATER: I'm asking my boss.

Chris, do you have that? I'm asking before -- I guess you're putting it up. So that's why he's not answering me. He's finding it.

MR. GEDDIS: Sorry. My

microphone was muted on my laptop. Do you want me to put it up?

MR. SLATER: Yep. Please. It's March 23, 2018 deposition transcript.

(Document Marked for identification as Exhibit Britt-12.)

THE WITNESS: Okay, what page?

BY MR. SLATER:

Q. We're going to go to page -- well, first I'm showing you the transcript. This is a deposition. I guess you were deposed in this matter, March 23, 2018, correct?

A. Correct.

Q. And that's the Scott versus Dyno, D-Y-N-O, Nobel, N-O-B-E-L, matter which was pending in Missouri, it looks like. Correct?

A. Yes.

MR. SLATER: Okay. Chris, could you go now to Page 12,

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please.
BY MR. SLATER:
Q. Looking at Line 6.
You were asked, "And you agree that a toxicologist cannot guarantee that a certain dose will never cause an individual" -- and then it says S-I-C -- "to a particular person, correct?"
Presuming you're being asked about a injury to a particular person, right? What was your answer?
A. I said, "Repeat that again." And then they repeated it. And then I said correct.
Q. Do you stand by that testimony now as a general proposition?
A. I think that's what I said. And I gave the caveat that as long as you have sufficient data within the dose exposure range that you can predict with a reasonable -- you know, with reasonable certainty what's going to happen.
Q. But you didn't say that when

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you were deposed in 2018, right? You just said correct, right?
A. Correct. I just -- I elaborated more today than I did back then.
Q. Are you aware of criticisms in the literature regarding evidence-based toxicology?
MR. GALLAGHER: Objection to form.
BY MR. SLATER:
Q. Are you aware that there are criticisms of the evidence-based toxicology approach in the literature?
A. I'm not aware of any.
MR. SLATER: Chris, do you have available -- you can take the transcript down. Do you have the Ruden article? That would be -- could we just put that up for a moment?
MR. GEDDIS: As an exhibit?
MR. SLATER: And for the transcript, we should have an

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exhibit also. If I missed saying that, the Scott transcript will be Exhibit, what -- is that 11.
MR. GEDDIS: Exhibit 12.
MR. SLATER: 12?
MR. GEDDIS: Yeah, and Ruden is 13.
MR. SLATER: Perfect.
(Document marked for identification as Exhibit Britt-13.)
BY MR. SLATER:
Q. This is an article, Exhibit 13 -- rephrase.
Article 13 is an article -- rephrase.
Exhibit 13 is an article titled "Evidence-Based Toxicology: Sound Science in New Disguise." Authored by Christina Ruden, Ph.D., and Sven Ove Hansson, Ph.D. Sorry if I mispronounced their names.
Have you seen this article before?

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A. I've seen it. I don't think I've ever read it. I know that I believe -- I believe Rob James and Guzelian may have responded to it. I'm not 100 percent sure.
Q. Did you speak to Robert James about this litigation at all?
A. No, no.
Q. So I think you're saying that you hadn't read this and you certainly didn't evaluate it, so you have no specific responses to what is stated in this article, I assume, right?
A. No. When was this? 2008. Yeah, I vaguely remember, I didn't participate. I don't know. I didn't read this.
MR. SLATER: Let's go to Page 305, please, Chris.
BY MR. SLATER:
Q. Okay. On Page 305, there's a heading on the left-hand side that says, "The origins of evidence-based toxicology."

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Do you see that?
A. Okay. I see that, yes.
Q. In the second paragraph, it says, "Guzelian et al.'s proposal is connected to both the tobacco industry and to litigation concerning potential occupational toxic injuries. Beginning with the former, the tobacco industry has a long history of neglecting and distorting scientific evidence."
Do you have any reason to disagree with what I just read?
A. I don't know anything about that. I have no opinion on that. I don't know where that -- I don't know. I have no opinion on that.
Q. Going down further towards the bottom of that paragraph, the last two sentences say, "The notion of 'sound science'" -- and sound science is in quotes -- "has now been thoroughly discredited. It appears that evidence-based toxicology is an attempt to relaunch the same controversial

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principle again under a name that sounds uncontroversial.
"Phillip S. Guzelian has a background as a consultant for the tobacco industry. During his time affiliated with Phillip Morris, he was paid about 100,000 per year.
"The second connection concerns Phillip S. Guzelian's litigation activities concerning potential occupation. He acts regularly as an expert giving testimony in litigation matters when workers claim to have sustained an occupational toxic injury."
I'm going to stop there.
Dr. Guzelian is who?
A. He is an M.D. toxicologist.
Q. What is your connection to him?
MR. GALLAGHER: Objection to form.
THE WITNESS: I have --
BY MR. SLATER:
Q. Is he your co-author?

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A. He was a co-author on an article. I've helped him with consulting years ago, in the past.
Q. Dr. Guzelian is one of your co-authors on the "Evidence-Based Causation in Toxicology: A Ten-Year Retrospective" article, correct?
A. That's correct.
Q. And has he worked with your company in the past?
A. Pardon me? Say it one more time.
Q. Has he worked with you in your company?
MR. GALLAGHER: Objection to form.
THE WITNESS: What do you mean by my company?
BY MR. SLATER:
Q. The companies that you've been employed by. Let's start with ToxStrategies. Has he worked with you during the time that you've been there?
A. Probably helped him a couple

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of times on a couple of matters since I've been at ToxStrategies.
Q. How about at Terra, your prior employer?
A. Yes, I did at Terra.
Q. Did he work for Terra?
A. No.
Q. So he's an outside consultant, but you've worked together on matters with him?
A. Yes.
Q. Coming back to this now, it says that he regularly acts as an expert giving testimony in litigation matters when workers claim to have sustained an occupational toxic injury.
Are you aware of that?
MR. GALLAGHER: Objection to form.
THE WITNESS: I'm not sure of the scope of the work that he does.
BY MR. SLATER:
Q. This says -- I'm continuing.

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"According to his own estimate, he has depositions on average four times a year during the last 20 years, and he has testified in court trials on average two to three times a year. For all of his medicolegal work, he has received approximately $500,000 to $1 million per year according to his own testimony. In all these cases but one has he testified on behalf of an industry defendant."

Were you aware of any of that information about his background as a testifying expert?

A. I know he testifies as an expert. I don't know how many times he's given depositions in the past. I don't know the accuracy of this information.

Q. Looking at the references, the last one is Number 30. I'll just start there and move forward. The reference at the end is, "Trial testimony of Phillip S. Guzelian in the case of Jesus Delaluz" -- D-E-L-A-L-U-Z -- "v. Safety Kleen Corporation."

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So it is a citation to actual trial testimony, right?

A. Yes.

Q. And Reference 29 about how often he testifies, that's the deposition of Phillip Guzelian in the same case, right?

MR. GALLAGHER: Objection to form.

THE WITNESS: Correct.

BY MR. SLATER:

Q. And if we keep going backwards to the bottom of the left-hand column when it talked about what he was paid by Phillips Morris, that's Reference 28, and it references documents relating to Guzelian's involvement with the tobacco industry, and it gives the exact place where the link -- it gives the link that can take you to those documents.

Do you see that?

MR. GALLAGHER: Objection to form.

THE WITNESS: I see that.

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BY MR. SLATER:

Q. Going to the next paragraph now, back where I was reading, this continues. "In 2004, he joined the advisory council of the Atlantic Legal Foundation, an organization that still uses the term 'sound science' in describing its principles for legal evidence. It is clear from transcripts of Phillip S. Guzelian's depositions that he acts efficiently in the interest of his corporate clients.

"His assessment of workers' claims that their diseases are work-related, he applies the same exceptionally high standards of evidence that are proposed in Guzelian, et al., 2005."

Do you see that?

A. Yes.

Q. And would you agree with me that in some, the application of the evidence-based toxicology approach in the types of cases being described here, for

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example where a worker is claiming to have been injured by a toxic exposure at work, the EBT approach heightens the bar to establish causation so it would be -- if accepted, would make it harder to prove a toxic exposure case than either Bradford Hill or weight of evidence methodologies, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: No, I don't agree that evidence-based toxicology -- it's a method anybody can use. It doesn't apply to any particular entity. That's why regulatory agencies and anybody can use it.

BY MR. SLATER:

Q. I understand anyone can use it. But the application of EBT in this type of case as I'm describing it, an exposure case to a toxic substance, if EBT is applied as described here, it would make it harder to prove a case or a

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toxic exposure because of the heavy weighting to human studies, correct?

MR. GALLAGHER: Objection to form.

THE WITNESS: I don't agree.

MR. SLATER: Yeah, I think that -- let's take a break. And then let's reconvene in about ten minutes. Is that okay?

THE VIDEOGRAPHER: The time now is --

MR. GALLAGHER: Ten minute?

THE WITNESS: Yeah.

THE VIDEOGRAPHER: The time now is 3:13 p.m. We're off the record.

(Short break.)

THE VIDEOGRAPHER: The time right now is 3:36 p.m. We're back on the record.

MR. SLATER: Chris, let's put up what we marked previously as Exhibit 129, as Exhibit 14 to this deposition.

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(Document Marked for identification as Exhibit Britt-14.)

BY MR. SLATER:

Q. Doctor, just so you know what I'm putting in front of you, this is the document that I referred to a little bit -- hang on. Sorry, let me start over.

Doctor, this is the press release that I referred to a little earlier.

So in fairness to you, you had asked if you could see it. I wanted to make sure that I could show it to you.

This exhibit was marked as Exhibit 129 during the depositions of the ZHP witnesses. You have not seen this, right?

A. I don't -- it doesn't look familiar. I don't believe so.

Q. Just to draw your attention to the part that I was reading from, just above that, there's a section that says,

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"For immediate release. Cranbury, New Jersey, July 13, 2018."

Do you see that?

A. Yes.

Q. And about the second half of it after they list the valsartan tablets that were recalled, ZHP told the world in this press release, "This product recall is due to the detection of a trace amount of an unexpected impurity, n-nitrosodimethylamine (NDMA) made by the manufacturer ZHP that is used in the manufacture of the subject product lots. This impurity has been classified as a probable human carcinogen as per International Agency for Research on Cancer (IARC) classification."

And then if you go down a little further, you get down to the part that I just read to you a little earlier today that states, "The exposure to the impurity n-nitrosodimethylamine (NDMA) that was detected in valsartan product line presents an unacceptable

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carcinogenic risk to the intended patient population."

Do you see that?

MR. GALLAGHER: Objection to form.

THE WITNESS: Let's see.

BY MR. SLATER:

Q. I'm sorry. Did you say that you do see that?

A. Yeah, I do see that now. Yes, I do see it.

Q. And just to close the loop, this is not something that you had seen previously to the best of your recollection, right?

A. No, no.

Q. Okay. And just in fairness and candor, I'm showing it to you because I don't like to necessarily use a document and have you wonder whether or not I was making up what I read to you. So I wanted you to see it.

A. That's fine.

MR. SLATER: We can take

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that down.
Chris, what I'd like to use next as Exhibit 15 is the textbook Principles of Toxicology.
(Document Marked for identification as Exhibit Britt-15.)
MR. SLATER: Let's go to the next page, please, which has the actual cover of the textbook. Perfect.
BY MR. SLATER:
Q. Doctor, do you recognize this as the cover of a textbook that was edited by Dr. Williams, Dr. James, and Dr. Roberts?
Do you recognize this?
A. Yes.
Q. If we go to the next page.
A. Okay.
Q. It shows that it's copyrighted in 2000, correct?
A. Yes.
Q. And if we go to the next

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page, the list of contributors, it lists you as one of the contributors. You wrote a chapter or a part of this book, correct?
A. Yes.
Q. If we go a few sections into the table of contents, there's Chapter 15. Chapter 15 is Properties and Effects of Pesticides. And it looks like that's the chapter that you wrote for this book; is that correct?
A. That's correct.
Q. Now, what I would like to do -- bear with me. This is a very long book. Let's go to Page 305, Table 13.13.
A. Page 35?
Q. 305. And if it's easier, Chris is scrolling through it. But I think you can't see the screen that well from where you're sitting.
MR. GALLAGHER: Sorry, what page?
MR. SLATER: 305.
THE WITNESS: Oh, 305.

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BY MR. SLATER:
Q. This is a Table 13.13 which is found in the section of the book or the chapter titled "Cancer and Our Environment," which is a chapter you did not write obviously, right?
A. Correct.
Q. And if we were to go back to it, this is the chapter titled "Chemical Carcinogenesis" authored by Dr. James and Christopher Saranko. So that would be Dr. James who you have co-authored some articles with and have worked with over the years, right?
A. That's correct.
Q. And if you look at the table, it says, "Agents listed in the Report on Carcinogens Eighth Edition from the National Toxicology Program as known or suspected human carcinogens."
And if we go down to the middle of the page, it lists "Agents reasonably anticipated to human carcinogens?"

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Do you see that title?
A. Yes.
Q. And then if we go to the next page, Page 306, where these chemicals are being listed, two of them are diethylnitrosamine, and dimethylnitrosamine, which are NDEA and NDMA, correct?
A. Yes.
Q. So in this textbook edited by Dr. James, he recognized that NDEA and NDMA are reasonably anticipated to be human carcinogens all the way back in 2000. That's what this establishes, correct?
A. Correct. This is similar to what the other regulatory agencies have stated and NTP still has the same categorization for NDMA and NDEA as anticipated, not known human carcinogens. NTP just has two rankings. Some agencies have more than one. They have four, three. NTP just has the two. So it's in the reasonably anticipated.

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Q. Got it.
A. So yes, I agree.
Q. Okay.
MR. SLATER: Chris, let's take that down now and go to our next exhibit which is going to be Exhibit 16.
(Document Marked for identification as Exhibit Britt-16.)
MR. SLATER: Which is the article -- rephrase.
Exhibit 16 will be the "Letter to the editor: Comments on recent discussions providing differing causation methodologies," please.
BY MR. SLATER:
Q. This is a letter to the editor submitted to Human and Experimental Toxicology in 2014 by yourself, Dr. James, Dr. Guzelian and someone named NC Halmes. Hope I'm pronouncing that correctly.

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A. Yes, yes.
Q. It's titled "Comments on recent discussions providing differing causation methodologies," correct?
A. Yes.
Q. What I'd like to do is turn to Page 110, please.
A. Okay.
Q. Looking at the left-hand column, the first full paragraph, if we go down about halfway, there's a sentence that starts, "For decades, regulatory agencies like the U.S. EPA have used animal data to identify the potential human health hazards and safe exposure guidelines for a given chemical exposure where the goal is to protect human health."
That's a true statement, correct?
A. That's true.
MR. GALLAGHER: Objection to form.
THE WITNESS: That's true.

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BY MR. SLATER:
Q. The next sentence says, "This is not equivalent to actually knowing human causation." And that sentence reflects back to what we discussed earlier as to the difference between the regulatory decision to protect human health versus the evaluation of causation for people that are exposed to the substance, correct?
A. That's correct.
Q. Looking at the next sentence, it says, "The International Agency for Research on Cancer (IARC) and U.S. EPA have long determined human causation based on human data of sufficient strength and consistency that are capable of confirming or denying the hazards suggested by animal studies."
That's a true statement, correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Correct.

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MR. SLATER: You can take that down. Let's go down -- we'll mark as Exhibit 17, the article "Evaluation Of the Carcinogenicity of 1,1-dichloroethylene," please.
(Document marked for identification as Exhibit Britt-17.)
THE WITNESS: Okay.
BY MR. SLATER:
Q. Exhibit 17 is an article titled "Evaluation of the Carcinogenicity of 1,1-dichloroethylene," and then in parentheses vinylidene -- I don't know if I pronounced that right -- chloride.
A. Vinylidene.
Q. Vinylidene. Thank you.
And there's a series of authors, including yourself and Dr. James, correct?
A. Correct.
Q. And this was published in the Regulatory Toxicology and Pharmacology Journal in 2002, right?

Page 302

A. Yes.
Q. The first sentence just gives us some context for this article. It says, "The U.S. Environmental Protection Agency has classified 1,1-dichloroethylene vinylidene chloride (VDC) as a 'capital C' Carcinogen and has developed an inhalation unit risk value and an oral cancer slope factor for this chemical. The development and use of these cancer potency estimates for risk assessment purposes are questionable."
So that's giving us an overview of the point of this article, correct?
A. Correct.
Q. Okay. Let's go now to Page 50.
A. Okay.
Q. I want to focus on the bottom right, the mode of action section, which states, "The mode of action by which VDC might produce a carcinogenic response is unclear."

Page 303

So that's just to give context. That's what this section of this article is talking about now, correct?
A. Yes.
Q. If you turn to Page 52, the continuation of that section.
MR. SLATER: Page 52. Perfect.
THE WITNESS: Okay.
BY MR. SLATER:
Q. In the top left, there's the carryover and it says, starting on the fourth line of this sentence, "Reitz" -- R-E-I-T-Z -- "et al, 1980, observed dose-related DNA alkylation following VDC inhalation in mice and rats. However, the extent of DNA alkylation was low, orders of magnitude less than that produced by the genotoxic carcinogen dimethylnitrosamine included in the study as a positive control (Reitz, et al., 1980.)"
Do you see that?

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A. Yes.
Q. What does that mean when you refer to a positive control?
MR. GALLAGHER: Objection to form.
THE WITNESS: Sometimes they use positive controls to get an effect to compare relatively what's going on with one substance versus another in a study.
BY MR. SLATER:
Q. And here you pointed out that NDMA was used as the positive control for this study of VDC, and that the DNA alkylation for VDC was orders of magnitude less than that produced by the NDMA which you characterize as "the genotoxic carcinogen dimethylnitrosamine," correct?
MR. GALLAGHER: Objection to form.
THE WITNESS: Yeah, I just was stating that comparatively speaking, in this -- these animal

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studies, that this one mechanism, that NDMA was a -- showed more of an effect than the vinylidene dichloride.
MR. SLATER: Thank you, Doctor. As of now, I have no other questions.
MR. GALLAGHER: All right. Can we take just five minutes?
MR. SLATER: Sure.
MR. GALLAGHER: We'll come back.
THE VIDEOGRAPHER: The time right now is 3:53 p.m. We're off the record.
(Short break.)
THE VIDEOGRAPHER: The time right now is 4:05 p.m. We're back on the record.
MR. GALLAGHER: Dr. Britt, we do not have any questions for you at this time. And we consider the deposition closed.
THE WITNESS: Thank you.

MR. SLATER: Thank you very much, everybody.

THE VIDEOGRAPHER: The time right now is 4:05 p.m. We're back on the -- we're off the record.

(Excused.)

(Deposition concluded at approximately 4:06 p.m.)

CERTIFICATE

I HEREBY CERTIFY that the witness was duly sworn by me and that the deposition is a true record of the testimony given by the witness.

It was requested before completion of the deposition that the witness, JANICE K. BRITT, Ph.D., have the opportunity to read and sign the deposition transcript.

____
MICHELLE L. GRAY,
A Registered Professional
Reporter, Certified Shorthand
Reporter, Certified Realtime
Reporter and Notary Public
Dated: October 6, 2021

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INSTRUCTIONS TO WITNESS

Please read your deposition over carefully and make any necessary corrections. You should state the reason in the appropriate space on the errata sheet for any corrections that are made.

After doing so, please sign the errata sheet and date it.

You are signing same subject to the changes you have noted on the errata sheet, which will be attached to your deposition.

It is imperative that you return the original errata sheet to the deposing attorney within thirty (30) days of receipt of the deposition transcript by you. If you fail to do so, the deposition transcript may be deemed to be accurate and may be used in court.

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E R R A T A
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ACKNOWLEDGMENT OF DEPONENT

I,______________________, do hereby certify that I have read the foregoing pages, 1 - 311, and that the same is a correct transcription of the answers given by me to the questions therein propounded, except for the corrections or changes in form or substance, if any, noted in the attached Errata Sheet.

____
JANICE K. BRITT, Ph.D. DATE

Subscribed and sworn
to before me this
_____ day of _______________, 20____.
My commission expires:_______________

____
Notary Public

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LAWYER'S NOTES

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